

Intellectual Property Rights and Agro-biodiversity

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Agrobiodiversity is the backbone of a nation's food security and the basis of economic development as a whole. The Intellectual Property Rights (IPR) regime is encouraging commercialization of seed development, monoculture, protection of new plant varieties, microorganisms, and genetically modified organisms. As a consequence, our rich biological diversity is being eroded irreversibly. This paper seeks to analyze the impacts of the international legal framework for the promotion of intellectual property rights on India's legal regime concerning the control over biological resources and inventions derived from biological resources. The paper analyses these enactments in the context of the move towards the control of biological resources and derived products through property rights. It also focuses on the issue of control over biological resources and derived products and seeks to provide a broader analysis of the changing international legal framework and its impacts on national law and policy-making concerning the management of biological resources. There was strong support for CBD and the fair and equitable sharing of the benefits arising from such use. TRIPS agreement of WTO vs CBD and gender implication of TRIPS was discussed. In addition, contribution of traditional knowledge and practices of local and indigenous communities for conservation was also emphasized for the effective maintenance of such knowledge systems.

Key words: Agrobiodiversity, IPR, Trade Related Intellectual Property Rights Agreement, World Trade Organization, Genetic resources

The last decade witnessed intensive debates on the issues of agro-biodiversity and intellectual property rights (IPRs). The two international treaties around which such debate has been revolving with significant consequences for public policy relating to intellectual property rights, biodiversity and associated knowledge systems, are the Convention on Biological Diversity (CBD) and the Trade Related Intellectual Property Rights (TRIPS) agreement of the World Trade Organisation (WTO). The CBD mandates countries to safeguard biodiversity and the traditions and knowledge of indigenous and other local communities associated with this biodiversity, and lays down the basic elements for access to that biodiversity and the associated knowledge systems. The TRIPS obliges party countries to modify their national IPR regimes to meet much-enhanced international standards, which would have significant implications for biodiversity and the associated knowledge systems. In addition, the World Intellectual Property Organisation (WIPO) and other international institutions are increasingly becoming active on the subject.

The essential principles of the CBD most relevant to the debate of IPRs over biological resources can be summarized as:

- the state has sovereign control over the biological resources within the limits of their national jurisdiction and shall ensure conservation and sustainable use of the same;

- while states shall have the authority to determine access to their biological resources, they shall endeavour to create conditions to facilitate such access;
- such access shall be granted on mutually agreed terms and subject to the prior informed consent of the party providing such access;
- the benefits of the commercial or other utilization of the genetic resources shall be shared in a fair and equitable way with the party providing such access; and
- the wider application of the knowledge, innovations and practices of indigenous and other local communities shall be done with the approval and involvement of the holders of such knowledge.

The aspects of the TRIPS agreement with implications for the above principles of the CBD are:

- it mandates developing countries to amend their existing regimes for the protection of intellectual property and adopt ones similar to those prevailing in the industrialised countries;
- it proposes an almost all-encompassing coverage under the patent system, and mandates that patents shall be available for inventions, whether products or processes, in all fields of technology. The coverage so defined is aimed at extending the fields of activity under patents to cover selected forms of life which were hitherto not considered patentable by most countries;

- As regards plant varieties, the TRIPS Agreement provides that protection has to be provided? either by patents or by an effective *sui generis* system or by any combination thereof?

In response to the debate at the international level, at the national levels there is considerable activity. Several countries (India, Mexico, Peru, Philippines, Costa Rica, Eritrea and Fiji) have come up with legislation, or coming up with other measures, which respond to the above treaties or in other ways deal with the relationship between IPRs and biodiversity. Of particular interest to many countries, especially in the 'developing' world, are the attempts to respond to the CBD-TRIPs debate through legislative and administrative measures in order to achieve the following:

- Protecting indigenous knowledge (traditional and modern) from being 'pirated' and used in IPR claims by industrial/commercial interests;
- Regulating access to biological resources so that historical 'theft' of these resources by the more powerful sections of the global society can be stopped, and communities/countries are able to gain control and benefits from their use.

All countries are now required to respond to this issue, especially given the following specific decisions taken at international forums:

- Decisions at successive Conferences of the Parties (CoPs) to the CBD, asking for more in-depth understanding, case studies, and other follow-up on the relationship between IPRs and biodiversity in general, and TRIPs and CBD in particular; and to work towards the protection of indigenous and local community knowledge, if need be through alternative IPR regimes.
- Decision arrived at the fourth meeting of the Subsidiary Body on Scientific, Technical and Technological Advice (SBSTTA) that recommend Parties not to approve field-testing of such technologies until appropriate scientific information can justify such testing, citing the precautionary approach and lack of reliable data. SBSTTA also invited the FAO, UNESCO, UNEP and other competent organizations to further study the potential impacts of such technologies.

IPRs Related to Agro-biodiversity

Intellectual Property Rights (IPRs), as the term suggests, are meant to be rights to ideas and information, which

are used in new inventions or processes. These rights enable the holder to exclude imitators from marketing such inventions or processes for a specified time; in exchange, the holder is required to disclose the formula or idea behind the product/process. The effect of IPRs is therefore monopoly over commercial exploitation of the idea/information, for a limited period. The stated purpose of IPRs is to stimulate innovation, by offering higher monetary returns than the market otherwise might provide.

While IPRs such as copyrights, patents and trademarks are centuries old, the extension of IPRs to living beings and knowledge/technologies related to them is relatively recent. In 1930, the U.S. Plant Patent Act was passed which gave IPRs to asexually reproduced plant varieties. Several other countries subsequently extended such or other forms of protection to plant varieties, until in 1961, an International Convention for the Protection of New Varieties of Plants was signed. Most signatories were industrialized countries, who had also formed a Union for the Protection of New Varieties of Plants (UPOV). This treaty came into force in 1968.

The types of IPR Agreement covers following, distinct types of (intangible) property, for which Intellectual Property (IP) is coined, namely:

- Copyright (and related rights): the rights of performers, producers of sound recordings and broadcasting organizations.
- Trademarks (including Service marks).
- Geographical Indications (including appellation of origin), Geographical Indications (GIs) cover place names used to identify products, which have a particular quality or other characteristics because they come from that place. Under the Agreement, GIs are protected, as Agreement provides "indications which identify a good as originating in the territory of a Member, or a region or locality in that territory, where a given quality, reputation or other characteristics of the good is essentially attributable to its GIs" (Article 22).
- Obligations (under TRIPS) only relate to GIs that are protected in their country of origin.
- Industrial designs.
- Patents (including the Protection of new Varieties of Plants (PVP).
- Patent gives a monopoly right [to patentee] to exploit the invention for a period of 17-20 years. Once a

patent is granted that patentee may give license [for the technology] to other individuals/companies.

- The Layout- designs (topographies) of Integrated Circuits and
- Undisclosed Information (including trade secrets and test data).
- Accordingly, depending upon the type of IP, the protection can be provided e.g. books, paintings and films come under copyrights; inventions can be patented and product(s) logos can be registered as trademarks; and so on.
- Inventions covered, under the Agreement, for purpose of protection must qualify following criteria:
 - they must be new, must involve inventive step(s), and are capable of industrial application.
 - In regard to the minimum standards, under the Agreement, each of the main element is defined namely: subject matter to be protected, the right(s) to be conferred, permissible exception(s) to those right(s), and the minimum duration of protection.

Plant varieties or breeders' rights (PVRs/PBRs) give the right-holder limited regulatory powers over the marketing of 'their' varieties. Till recently, most countries allowed farmers and other breeders to be exempted from the provisions of such rights, as long as they did not indulge in branded commercial transactions of the varieties. Now, however, after an amendment in 1991, UPOV itself has tightened the monopolistic nature of PVRs/PBRs, and some countries have substantially removed the exemptions to farmers and breeders.

Historically, plant varieties had been exempted from the international patent regime in deference to farmers' traditional practices of saving and exchanging seeds. Industrialized countries, however, have been debating on the issue of PBRs as a form of monopoly to encourage plant breeding activity. This culminated in the conclusion of the International Convention for the Protection of New Varieties of Plants (UPOV Convention) in 1978, which was amended in 1991, further strengthening the monopolistic hold of plant breeders. The parties to the UPOV Convention, included, until recently, mainly Organization for Economic Co-operation and Development (OECD) countries. The TRIPS Agreement now extends the requirement to protect plant varieties to all World Trade Organization (WTO) Member States.

In addition, in many countries, patents with full monopolistic restrictions are now applicable to plant

varieties, microorganisms, and genetically modified organisms. In 1972, the U.S. Supreme Court ruled that microbiologist Ananda Chakrabarty's patent claim for a genetically engineered bacterial strain, was permissible. This legitimized the view that anything made by humans and not found in nature was patentable. Finally, several patent claims have been made, and some granted, on human genetic material, including on material that has hardly been altered from its natural state?

Till very recently, these trends were restricted to some countries, which could not impose them on others. However, with the signing of the TRIPs agreement, this has changed. TRIPs requires that all signatory countries accept some 'effective' form of IPRs on plant varieties, either patents or some *sui generis* (new) version. TRIPs allows countries to exclude animals and plants *per se* from patentability. However, the provisions above have serious enough implications, for no longer are countries allowed to exclude patenting of life forms altogether (micro-organisms have to be open for patenting). Nor is there likely to be a great amount of flexibility in evolving *sui generis* systems of plant variety protection, for the term 'effective' may well be interpreted by industrial countries to mean a UPOV-like model.

The history of IPRs shows that the monopolistic hold of governments, corporations and some individuals over biological resources and related knowledge is continuously increasing. As the examples noted in the Introduction show, a substantial amount of this monopolization is built upon, and through the appropriation of, the resources conserved and knowledge generated by indigenous and other local communities.

The Intellectual Property Right in India

Under article 70.8 and 70.9 of the TRIPS agreement, India is obliged to amend its Patent Act to provide legal coverage to global inventions on pharmaceuticals and agro-chemicals in the form of product patents starting January 1, 2005. While the debate continues as to how best protect indigenous knowledge and provide for biosafety under TRIPs, foreign multinationals were pressuring India to adopt Exclusive Marketing Rights (EMRs) in the interim. India received an adverse judgment delivered by the Dispute Settlement Body (DSB) of the WTO on a case relating to pharmaceutical and agro-chemical products filed by the US and earlier by the EU. Now India has to amend its patent law before April 19, 1999 to comply with the DSB judgment. This has created an atmosphere of desperation in the government as law

makers hurry to adhere to the WTO deadline. In accordance with the TRIPs agreements, countries that do not provide for product patents before 2005 are required to provide a mailbox facility for receiving applications and grant EMRs to companies with patented products and marketing approval in any WTO signatory country prior to January 1, 2005.

The Rajya Sabha (Upper House of the Indian Parliament) passed the Patent (Amendment) Bill 1998 on 23 November, 1998, which provides for EMR's. The President of India promulgated the Patent (Amendment) Ordinance, 1999 (No. 3 of 1999) on January 8 that also provides for EMR's on pharmaceuticals and agri-chemicals. Ordinances immediately become law for the duration of 6 months. Thus, the Patent Ordinance has been approved in order to by-pass the patent system and grant EMRs as a statutory right to pharmaceuticals and agri-chemicals. The Patent Bill, however, which, if approved, would become an Act, is to come up for approval during the current Budget Session of the Lok Sabha (Lower House). EMRs essentially guarantee a monopoly market to "claimants" without means for review and rejection of biohazardous or biopirated products. Indeed, EMRs are a claim to marketing as a right, not an approved privilege. EMRs are granted to foreign companies merely on the basis of foreign patents, even if these foreign patents are based on the piracy of Indian indigenous knowledge, and can be used to establish market monopolies in India, thus destroying the socio-economic basis of survival a large number of India people. On the basis of biopiracy patents and patents granted in any other country after 1995, a corporation can claim exclusive marketing monopoly on formulations based on ginger, pepper, harrar, amla, etc. with only minor modifications in methods of extraction and processing. Further, since many of the plants we use for medicine are also used for food, EMRs on formulations based on indigenous knowledge will create monopolies on food items, raise prices, and thus undermine food rights and food security.

The Indian government has been supporting EMRs under the myth that they will promote scientific research in India. Since the EMR ordinance is for exclusive marketing rights in India on the basis of foreign patents and it by-passes the patent system, Indian Research and Development (R&D) will not be protected or enhanced. In fact Indian R & D budget will shrink as exclusive monopolies destroy the economy. The safeguards measure

as given under the Patent (Amendment) Bill 1999 or the Patent Ordinance 1999 is very vague and diluted. India has introduced a compulsory licensing provision to curb unduly price increases by MNC drug manufacturers. This gives the government the right to grant a license to produce drug to any company even if another company is given an EMR. However, compulsory licensing, as stands in the Bill and the Ordinance offers no safeguard since compulsory licensing applies to manufacturers, while EMR's are rights to sell. Compulsory licensing is therefore a fictitious safeguard. Interestingly, the US has already filed a complaint to the WTO against this illusionary provision of compulsory licensing.

Price control mechanisms on medicines or an India food item sold as medicinal formulations (e.g. ginger, haldi, pepper, etc.) will also not work, since EMR's will be granted as statutory rights in which government intervention will be treated as illegitimate. Once EMRs are granted, foreign corporations can not be forced to sell medicines and agricultural chemicals at cheaper prices. In fact, the whole point of EMRs is to be able to bypass the price regulation system already in place in the country, which ensures that the essential commodities of food and medicine are accessible to the people of the country, especially the poor. Therefore the claim of the government on the various aspects of safeguards are totally misleading and there are absolutely no safeguards available to protect the national interest in the EMRs system. Rather than adopt the EMR route, India should draft a new patent law that addresses the challenges of the age of biology. Strengthening the patent system allows for examination of foreign applications on the grounds of patentability and protection of environmental, human, and animal health and moral order. While EMRs will provide no protection from the introduction of biohazardous material and the perpetuation of biopiracy, a strict and strong patent law has the potential to guard the basic right of the Indian people to food and health from the pharmaceutical and agri-chemical MNCs.

IPRs vs. Biodiversity

The CBD has two interesting provisions relating to IPRs. One, Article 16.5 states that Contracting Parties shall cooperate to ensure that IPRs are 'supportive of and do not run counter to its (the CBD's) objectives'. However, this is 'subject to national legislation and international law'. Another, Article 22 states that the CBD's provisions will not affect rights and obligations of countries to other 'existing international agreements, except where the

exercise of those rights and obligations would cause a serious damage or threat to biological diversity'. Read together and in the spirit of the CBD, many people have said there is a basis for countering the runaway march of the IPR regimes described above. But in order for this argument to hold, the actual impacts of IPRs on biodiversity need to be examined. This is a difficult subject, for direct impacts are hard to perceive. However, the following aspects must be considered:

- Current IPR regimes have allowed industrial and commercial interests to appropriate the resources and knowledge of resource-rich but economically poor countries and communities, further 'impoverishing' them or excluding them from technological improvements.
- IPRs are likely to greatly intensify the trend to homogenize agricultural production and medicinal plant use systems. In agriculture, for instance, any corporation which has spent enormous amounts of money obtaining an IPR, would want to push its varieties in as large an area as possible. The result would be serious displacement of local diversity of crops (though of course IPRs would not be the only factor in this).
- Increasingly species-wide IPRs (such as those on transgenic cotton and soybean) could stifle even public sector and small-scale private sector crop variety development.
- Having to pay substantial royalties to industrial countries and corporations could greatly increase the debt burdens of many countries. This could further intensify the environmental and social disruption that is caused when debt repayment measures are taken up, such as the export of natural products.
- Farmers who innovate on seeds through re-use, exchange with other farmers, and other means, would be increasingly discouraged from doing so if the tighter regimes that UPOV 1991 sanctifies are imposed on their countries; these regimes would also increase the economic burden on farmers, further discouraging innovation.
- The ethical aspects of IPRs are serious, and to many communities and people the most important reasons for opposing current IPR regimes: the patenting of life forms (abhorrent to many traditional societies and modern conservationists because of its assumption that nature exists apart from, and solely for the use of, humans); the privatization of knowledge

(repugnant to many societies which held knowledge to largely, though by no means only, in the public domain); and others.

TRIPs vs. CBD

The TRIPs agreement is only likely to greatly intensify the impacts outlined above. In particular, its attempt to homogenize IPR regimes militates against a country's or community's freedom to choose the way in which it wants to deal with the use and protection of knowledge. Equally important, it contains no provision for the protection of indigenous and local community knowledge. Such knowledge, because of its nature, may not be amenable to protection under current IPR regimes. Finally, it has no recognition of the need to equitably share in the benefits of knowledge related to biodiversity. Indeed, it legitimizes the conventional inequities that have characterized the interactions between the industrial-commercial use of biodiversity-related knowledge, and the community/citizen use of such knowledge.

The negative impacts of TRIPs on the three objectives of the CBD are already beginning to be felt, or threatened, in some countries. There is an urgent need to explore whatever spaces are available within existing regimes, to counter these threats, and to examine alternative regimes which have conservation, sustainable use, and equitable benefit-sharing built into them.

TRIPs vs. CBD in India

India is currently considering two laws to follow up TRIPs and CBD: the Plant Varieties and Farmers' Rights (PPV&FR) and the Biological Diversity Act (BDA), respectively. The PVPFR is supposed to be India's *sui generis* plant variety protection regime (as per Article 27(3)b of TRIPs). The Biodiversity Act (BDA) on the other hand, is being conceived as a law to implement the CBD provisions in relation to access to genetic resource and sharing of benefits from use of such resources. However, in several ways these proposed laws are not in harmony:

- The Biological Diversity Act (BDA) provides for the protection of local community rights in a broad sense, and recognizes that members of the local community, acting through the Biodiversity Management Committees at the local level, shall be consulted before biological resources and the knowledge and information of the community pertaining to the same is accessed. The PVPFR, however, contains only a narrow definition of farmers'

rights (the right to reuse, exchange, and sell except as branded product) protected plant varieties; it does not provide for the protection of farmers' own varieties (which are unlikely to pass the stringent tests of novelty, distinctiveness, etc.) but rather focuses on benefiting formal sector plant breeders.

- Whereas the Biological Diversity Act (BDA) explicitly provides for benefit-sharing measures with local communities, the PVPFR has no such provision.
- The BDA also puts in place a mechanism for Prior Informed Consent (PIC) of the concerned authorities, and in consultation with the affected local PVPFR however does not contain any provision mandating PIC when varieties developed by farmers are accessed for research and commercial purposes. Its provision enabling claims by farmers and communities to claim compensation upon proving they had made a 'significant contribution' to the variety granted protection under the Act, represents an unfair deal for farmers. In effect, it puts in place the grounds for an unfair legal battle between a large breeding corporation with economic and legal resources, and a farmer/farming community who is at a distinct economic disadvantage?
- The BDA attempts to include local community representatives at various levels of decision-making and has provisions to the effect that the decision making authorities at the state and national levels shall consist of representatives of local communities. The PVPFR, however envisages a bureaucratic management structure with no representation from local farming communities or NGOs;
- Whereas the BDA requires impact assessments of proposed projects that are likely to have adverse impact on biological diversity to ensure that they are in harmony with biodiversity conservation and sustainable use, the PVPFR does not require any such assessments for plant variety protection applications.

Though essentially favouring the further expansion of current IPR regimes, there are some provisions in TRIPs that can be exploited by communities and countries interested in protecting their interests against those of dominant industrial-commercial forces:

- Article 8 allows for legal measures to protect public health/nutrition, and public interest; though environmental protection is not explicitly built into this, it could be justified as being in 'public interest'.

Unfortunately, this clause is subject to 'the provisions of TRIPs', which leaves wide open the interpretation of its applicability.

- Article 22 allows for the protection of products which are geographically defined through "geographical indications". This could help protect some products which are known by the specific locations in which they have originated. It is debatable whether, for instance, Basmati rice could have been protected in this manner (the name does not derive from any location, but the variety is known to come from a particular geographical area). Countries like India already has domestic legislation on this.
- Article 27(2) allows for exclusion, from patentability, inventions whose commercial use needs to be prevented to safeguard against 'serious prejudice' to the environment. This is somewhat convoluted, because a country will first need to determine such serious prejudice, justify the prevention of commercial use, and then only be able to justify non-granting of patents.
- Article 27(3) allows countries to exclude plants and animals from patentability, and also plant varieties, so long as there is some other 'effective' form of IPR to such varieties. As mentioned above, what is 'effective' is likely to be determined by powerful countries, in which case the almost patent-like regime being advocated by UPOV could well be pushed. However, an exceptionally bold country could well experiment with completely different *sui generis* systems, and face up to any charges that are brought against it at WTO.

As mentioned above, both Article 16(5) and Article 22 provide countries with some maneuverability with regard to IPRs. If indeed a country can establish that IPRs run counter to conservation, sustainable use, and/or equitable benefit-sharing, it should be justified in excluding such IPRs. However, the caveat 'subject to national legislation and international law' may well make this difficult, since TRIPs is also 'international law'. Between TRIPs and the CBD, which holds legal priority? Legal opinion would perhaps be that TRIPs, being the later treaty, would supersede CBD in case of a conflict. However, given that CBD deals much more with the protection of public interest and morality, which TRIPs acknowledges as valid grounds for any measures that countries want to take, it could be argued that CBD's provisions should supersede those of TRIPs. This interface has not yet been

tested in any active case in the international arena; only when it does, will we know what interpretation is likely to hold. The CBD, unfortunately, is at a serious disadvantage as it does not yet have a dispute resolution mechanism of its own, unlike the WTO.

Perhaps the most crucial provision within CBD may be Article 8j, which requires countries to respect and protect indigenous and local community knowledge, ensure that such communities are asked before using their knowledge for wider society, and further ensure the equitable sharing of benefits arising from such use. Built into this provision are the seeds of a radically different vision of protecting knowledge and generating and sharing benefits from it. Discussions within the CBD forums, including at successive Conferences of Parties (CoPs), have demonstrated this potential, especially since a wide range of indigenous and local community groups have used the forums to push their case.

Under the changing IPR Regimes, a combination of the relevant clauses in TRIPs and the CBD, can be used to argue for modifications in existing IPR regimes which can help to safeguard public interest. Many people have argued, for instance, that apart from the usual criteria of novelty, etc. that are required of an IPR applicant, the following should also be sought as part of the application:

- Source (country/community/person) of the material or information that has gone into the produce/process for which an IPR is claimed;
- Proof of prior informed consent from the country and community of origin;
- Details of the benefit-sharing arrangements entered into with the community of origin, wherever applicable.

Countries like India have also suggested that all IPR applications, which are related to biodiversity and biodiversity-related knowledge, should be posted on the Clearing House Mechanism (set up under the CBD), giving concerned countries and communities/persons an opportunity to object if they feel that their rights have been violated. These suggestions have, of course, not yet been accepted at an international level, but are being built into some domestic legislation.

A number of NGOs and individuals have advocated various forms of intellectual rights regimes which recognize the essentially community-based nature of a lot of biodiversity-related knowledge. At an international level, for instance, an alternative to UPOV has been

suggested by Indian NGOs Gene Campaign which focuses equally on farmers' and breeders' rights. There have also been suggestions for recognition of concepts such as Traditional Resource Rights, which encompass not just intellectual but also physical resource and cultural rights. Countries like the Philippines are attempting to try such regimes, though the experience is far too short to make any judgments of their efficacy. In addition, WIPO and other international agencies are also studying the possibilities of protecting indigenous and local community knowledge through alternative regimes.

The power invested under TRIPs in the 'Dispute Settlement Body' and the 'TRIPs Council' over-ride the jurisdiction and mandates of CBD and Biosafety Protocol (BP), as also the Convention on International Trade in Endangered Species (CITES), ILO Conventions (1957/107; 1989/169) dealing with the protection of the rights of indigenous people and local communities, the Declaration of the UN's Economic and Social Council (ECOSOC) on the rights of indigenous peoples (especially resolutions 1990/27 and 1991/31) and FAO's international undertaking on plant genetic resources. This power can nullify concepts and principles which are essential for sustainable development and environmental quality, and which were achieved after several rounds of international deliberations: The concept of sovereignty, the 'precautionary', 'internalising' and 'polluter-pays' principles, and equitable benefit-sharing of genetic resources. Several agreements within WTO, particularly TRIPs (Article 27(3)b), directly or indirectly, affect biodiversity conservation.

With respect to intellectual property, TRIPs (Articles 3 and 4) requires member-states to observe the principles of 'national treatment' and 'most-favoured nation'. Of seven forms of intellectual property protection (copyright, patenting, plant variety protection, industrial design, geographical indications, lay-out design of integrated circuits, and trade secrets) the three most important for biodiversity and biosafety are patents, Plant Variety Protection (PVP) and geographical indications. Article 27 of TRIPs sets the framework of the patent regime while Article 31 provides for compulsory licensing. Indian Parliament has already passed the 'Protection of Plant Varieties and Farmers' Rights Act 2001', following the provisions of UPOV. Since the emergence of the WTO regime, three Articles of CBD have assumed greater relevance: Article 8(J) which relates to the preservation and maintenance of traditional knowledge systems of

local communities, through equitable sharing of benefits; Article 16 covering the whole issue of access to and transfer of technology including biotechnology; and Article 15.1 pertaining to the rights over genetic resources.

Indigenous and Local Community Rights

Article 8 (J) imposes a major responsibility on nations to establish a critical balance between biodiversity conservation and the protection of the rights of the indigenous and local communities. The debate on Intellectual Property Rights (IPRs) and on Article 8(J) took an interesting turn at the fifth meeting of the Conference of Parties (nations), at Nairobi in May 2000, with the Working Group II recommending the continuous involvement of indigenous people while the intellectual regime was being implemented. It also called for, *inter alia*, the full and direct participation of indigenous and local communities including women; recognition of the collective dimension of indigenous knowledge and the issues related to Mutually Agreed Terms (MAT)/Prior Informed Consent (PIC); and direct involvement of indigenous technical experts. The report recommended that parties support the development of traditional knowledge registers, recognized that the maintenance of such knowledge requires maintenance of cultural identities and the material base, and emphasised the need for indigenous and local communities to control and determine MAT/PIC arrangements so as to make informed decisions. The Working Group set out a two-phase approach for implementation. The first phase includes tasks that address participatory mechanisms, strategies and trends, benefit-sharing, exchange and dissemination of information, and other legal elements. The second phase would include participatory processes for conservation and systematic use, and other monitoring elements.

Access to and Transfer of Biotechnology

Article 16 covering 'Access to and transfer of technology' particularly emphasizes that transfer of technology should be provided and/or facilitated under fair and most favourable terms. In the case of patents and other property rights, such access and transfer are to be provided only after honouring IPRs. It further stipulates that measures be taken at the policy level to ensure that the private sector facilitates access to joint development and transfer of technology, subject to national and international laws.

Access to Genetic Resources

Article 15 on access to genetic resources provides a framework for establishing that States have sovereign

right over their natural resources. It says that access to genetic resources shall be subject to the PIC of the Contracting Parties providing such resources. PIC is an important mechanism as it ensures community participation in decision-making. The royalty-sharing experiment between the Kani tribe and the Tropical Botanical Garden and Research Institute (TBGRI), Thiruvananthapuram (Kerala), is an example of this.

Points of Conflict

The points of conflict are:

- a) Recognition of national sovereignty under the CBD implies that countries have the right to prohibit IPRs on life forms (biological resources). TRIPS overlooks this right by requiring the provision of IPRs on micro-organisms, non-biological and microbiological process, as well patents and/or *sui generis* protection on plant varieties.
- b) The CBD gives nations a legal basis to demand equitable benefit sharing arising from the use of biological resources and associated traditional knowledge, practices and innovations. TRIPS negates the broad historical contributions made by the communities in the IPRs regime and establishes the monopolistic control of the patent holder. Thus, there will be no legal synergies between these two sets of rights, and
- c) The CBD gives Parties legal authority to provide access based on PIC and MAT to biological resources. TRIPS ignores this authority. d) The CBD places public interest and common good over private property and vested interest. TRIPS does the opposite. To deal with this conflicting situation, CBD must be fully developed as an effective international instrument if it is to promote the sustainable use and conservation of biodiversity, based on community control of resources.

For example, since the WTO has an effective dispute redressal system, there is an urgent need for the establishment of a similar system under the CBD in the light of Article 22 (1) that states that the provisions of CBD 'shall not affect the rights and obligations of any party deriving from any existing international agreement except where the exercise of those rights and obligations would cause a serious damage or threat to biological diversity. This would bring the CBD at par with the WTO Agreements *vis-à-vis* biodiversity conservation and the sustainable use of biological resources.

Taking into account the precautionary approach, the objective of the Biosafety Protocol, under the CBD, is 'to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of Living Modified Organisms (LMOs) resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on trans-boundary movements' (Article 1). Surprisingly, the definition of LMO (Article 3) does not include 'product thereof' and as such these would be internationally unregulated. However, 'the protocol shall apply to the trans-boundary movement, transit, handling and use of all LMOs that may have adverse effects... 'in accordance with its objectives (Article 4), and exclude LMOs which are pharmaceuticals (LMO-P) for human uses and are covered by other international agreements or organizations (Article 5). LMOs intended for direct use as food, feed or for processing have also been excluded from the regular Advanced Informed Agreement and risk assessment (Article 7.2), but alternative procedures have been set.

GATT

Three major provisions of the WTO, if narrowly interpreted, may have serious implications for the implementation of Biosafety Protocol (BP). GATT provides justification for trade barriers that are necessary to protect animal and plant life and health, and relate to the conservation of exhaustible natural resources. Using these provisions, Trade Related Environmental Measures (under GATT) may be invoked as per the requirement of BP. However, the existing GATT panel has not taken measures comparable with the biosafety measures involving questions of scientific uncertainty, ethical and socio-economic considerations, and the diverse levels of risk-awareness in different WTO Parties.

Sanitary and Phytosanitary Measures

The Agreement on Sanitary and Phytosanitary Measures (SPS) under WTO has refined the rights and obligations of the Parties while adopting measures to protect human, animal and plant life, and health risks arising from the introduction of food, disease-carrying or disease-causing organisms, including the entry and establishment of pests. It is to be noted that Article 2 (2) of the SPS requires parties to base their SPS measures on scientific principles and not to maintain these without sufficient scientific evidence. This means that the importing countries might

not accept the safety measures which are adopted by exporting countries in the absence of scientific certainty. Besides, the LMO labelling scheme could still be defended by the importing countries as it would not create 'arbitrary or unjustifiable discrimination', or represent a 'misguided restriction' on international trade.

Technical Barriers to Trade

The Agreement on Technical Barriers to Trade (TBT) aims to ensure that parties do not use domestic regulations, standards, testing and certification procedures to create unnecessary obstacles to trade.

- It has been designed to prevent arbitrary standards from being used to protect industries from foreign competitors. It encourages international standards that producers must comply with to gain access to different markets.
- The TBT agreement includes obligations relating to the preparation, adoption and application of technical regulations and standards, and the procedures for assessing whether the products conform to these regulations and standards. The agreement also imposes requirements for labelling of products.
- It is to be seen how countries not party to the CBD and the BP use these WTO agreements from the perspective of biosafety concerns. The preamble of the Biosafety Protocol reflects the compromise reached at Cartagena in May 2000.
- As the preamble is weaker than the text agreed upon earlier in Miami, the substantive articles are also rendered vulnerable to misuse due to the specific provisions in the protocol that refer to other international obligations.

Apart from the specific points of conflict between the CBD and the WTO, there are broader issues of lack of compatibility between the various WTO agreements and the CBD, including the Biosafety Protocol. These include:

- The enhancement of global trade through implementing the WTO Agreements may aggravate the unsustainable use of biodiversity, which is contrary to the objectives of CBD.
- The increased transportation activity and infrastructure development to promote global trade may have an adverse impact on the functioning of ecosystems, which could result in biodiversity losses.
- The trans-boundary movement of biological products, including LMOs in trade may result in the accidental

introduction of alien species which may lead to destabilization of native species.

- The liberalization of trade and investment may intensify the direct and indirect adverse impacts on biodiversity and the supporting habitats.
- The WTO agreements may interfere with the international/ national subsidies as incentives to the industry, or with conservation laws and policies which seek control of traded goods.
- Moreover, built into the WTO agreements are various policy interventions for trade enhancement which may completely ignore the cost required for maintaining the environmental functions of the major habitats, thus, resulting in unsustainable production or trade in certain sectors.

Resolving the Conflicts

If the WTO Agreements and the CBD (inclusive of the Biosafety Protocol) are to be implemented in the interest of human survival and well-being, urgent measures are required to be taken to ensure that the objectives of CBD are not undermined by the narrow agenda of WTO Agreements, particularly of TRIPS. These measures would include: First, that nations recognize and affirm in law the primacy of the CBD over the TRIPs in the areas of biological resources and traditional knowledge systems. Second, the collective rights of indigenous and local communities to freely use, exchange and develop biodiversity should be recognized as a priori rights and be placed over and above private intellectual property rights. This has to be reflected in legislation and public policy at the national level. Third, the implementation of TRIPs in developing countries should be challenged so as to make these compatible with the provisions of the CBD. Fourthly, during the review of TRIPs, it should be ensured that there is an option to exclude all life forms and related knowledge from the IPR system.

If such measures are taken by the parties concerned, the Convention on Biological Diversity and the Biosafety Protocol could provide an innovative approach to the interface of trade and environmental concerns, and set a precedent for 'sustainable trade agreements' so that the potential value of biological resources can be optimised on a equitable basis for the welfare of human beings.

Gender Implications of TRIPS

Viewed from the point of women who are poor and are struggling with issues of sustainable livelihoods in farming

and other sectors of the economy, the fundamental issues in the intellectual property rights debate are fourfold:

- One basic challenge is access to affordable medicines – for HIV/AIDS, infectious diseases and reproductive health. HIV/AIDS and infectious diseases impact upon women on multiple levels. They ravage the body of the usually under nourished women (a problem linked to underlying customary practices regarding the distribution of food between boys and girls, men and women within families), with significant implications for women's morbidity and mortality. Furthermore, these diseases increase women's caretaking burden in the home and community.
- The second set of challenges that TRIPs poses for women is around access to seeds for food production, food security and adequate nutrition.
- The third set of challenges is access to, and control of, land; the use of natural and genetic resources; and access to technology and fertilizer for improving the chronically low productivity of women farmers.
- The fourth TRIPs-related issue is the level of the recognition of, and compensation for, traditional and local knowledge among women as compared to men.

A patented and more access restrictive IPR world is likely to exacerbate women's relatively restricted condition in subsistence farming and increase their poverty. Undeniably, women, more than men, experience barriers in accessing credit, land and technology. This, coupled with the trend in trade reform of removal of subsidies and the general deteriorating conditions for local agricultural production, is bound to worsen the plight of women in subsistence farming further. IPRs also pose other more direct threats:

- The patenting of seeds and micro-organisms, which is associated with a significant rise in the cost of farming inputs;
- The increasing privatization of genetic resources and agricultural knowledge, some of which is occurring via biopiracy and bio-prospecting;
- The trend towards the concentration of farming in the hands of wealthy farmers and multinational corporations (MNCs). This is a phenomenon that is partly due to the rise of industrial agriculture, but is likely to be exacerbated by TRIPs which can bring about the monopolization of knowledge and resources in the areas of agriculture, medicines and pharmaceuticals.

1) *Resource-Poor Farmers*

Patents on seed and microorganisms such as algae, bacteria and fungi increase the cost of seed and fertilizers. Increasingly, many of the inputs needed for farming must be obtained in the market. Patents and more expansive breeder rights encourage restrictions on the exchange, use or sale of seeds by farmers. This puts resource-poor farmers, many of whom are women, at a severe disadvantage. Given existing disparities between women and men's access to cash and credit, which are necessary to facilitate the purchase of fertilizer and seed, women farmers tend to have a higher risk of falling into chronic indebtedness. Male farmers, as a group, tend to have greater access to cash and credit. Men also tend to plant hybrids as a cash crop). Such crops not only require extensive and intensive land use, including the application of pesticides, but also are often very labour intensive. The impacts on women are twofold: in many cases, they lose access to fertile land for their own production, and their labour is also relied upon for weeding and other tasks. Not only is their workload increased, but they also suffer greater exposure to pesticides.

2) *Rising Expenses of Farming*

In the context of women's already weak or non-existent ownership and insecurity of land tenure, the rising expenses of farming are likely to severely compromise the livelihood of women farmers and increase their marginalization and impoverishment. Protection of plant varieties (PPV), which is urgently framed in terms of the rights of commercial breeders, will affect female and small farmers' access to germplasm as well as to scientific knowledge. Through its focus on monoculture, PPV will tend to retard diversity in plants and thus have an adverse impact on biodiversity with important consequences for local food security, including decreased nutrition. Biodiversity is also critical to the survival and future growth potential of women farmers who have little access to mechanized tools, equipment and chemicals to manage and manipulate the soil, create and divert streams of water, and improve crop yields. Biodiversity helps in the promotion of soil fertility, and soil conservation and management, as well as affecting the nutritional content of plants and agricultural output. Women have been critical in the maintenance and

preservation of biodiversity in many communities for centuries.

3) *Protecting Traditional Knowledge*

Central to this issue is the nature and kind of protection provided for traditional knowledge in terms of recognition of the contribution of female and male farmers, and the nature of provisions for benefit sharing and prior consent. To what extent do these take account of women's inventions and contribution to natural and genetic resource management? Who is consulted in establishing benefit sharing and prior consent agreements? What is the process for enhancing the traditional knowledge of men and women? This is a particularly difficult area. The wider issue of whose consent is asked for, and who gains or loses from the privatization of collective knowledge, is related to the role and contribution of women, as well as the structural and social limitations they face within the formal and informal agricultural sector. It is normally the case that women have a triple burden in undertaking the traditionally prescribed role of caring for children and the elderly, engaging in food production as well as household duties and carrying out the tasks of enhancing, developing and transmitting agricultural knowledge and know-how in the community. Yet this is often not recognized, acknowledged or compensated for in models for protecting traditional knowledge or in benefit-sharing agreements.

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