Fitting Plant Variety Protection and Biotechnological Inventions in Agriculture Within the Intellectual Property Framework: Challenges for Developing Countries*

The TRIPS Agreement in Article 27(1) sets out the general criterion of patentabable subject matter by providing that "patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application". The Agreement does not make any reference to biotechnology, but Article 27 (3)(b), dealing with IPR protection of life forms, is very expansive in approach. Whereas it allows Member States to exclude from patentability plants, animals and essentially biological processes for the production of plants or animals, as well as plant varieties, it makes microorganisms, non-biological and microbiological processes as patentable subject matter. Plant varieties, however, are to be protected through an effective IPR system, either by patents or by an effective *sui generis* system or by any combination thereof.[1]

This two-fold mandate of the TRIPS Agreement – making biological inventions patentable and plant varieties protectable under IPRs has wide implications for developing countries, particularly South-Asian countries. Like many other developing countries, agriculture remains the key to sustainable development in South Asia where about 70 percent population of the region lives in rural areas and agriculture provides the livelihood to two-thirds of South Asia's workforce and marked by small land-holdings, with 80 percent holdings have an average size of 0.6 hectares.[2] Most of these people are resource poor and illiterate. What happens to agriculture and to small farmers will make a big difference for the people of the region and will also affect the over-all development of these countries. While according intellectual property protection to plant varieties and biotechnological inventions, the poverty of the region and the customary practices of agriculture of the farming community have to be kept in sight, since bottom-line of the protection is exclusivity and monopoly and any unauthorised use of the protected subject-matter is illegal.

The intellectual property protection of biotechnological inventions and plant varieties has raised a host of issues critical to the very sustainability and economic growth of developing countries, as it is not confined solely to giving incentives to the private sector. It is closely linked with the rights of farmers. Crucial issues in this context are: whether and how IP protection would promote research and innovation in plant varieties; how to ensure transfer of technology relevant to the needs of developing countries; how this protection would affect the cost and access of farmers to seeds/propagating material and other inputs, such as pesticides, herbicides and fertilizers; how the

---

* The author is Professor of Law, University of Delhi, Delhi; Former President of International Association for the Advancement of Teaching and Research in Intellectual Property (ATRIP) 2001-2003.

[1] In furtherance to this mandate, many Asian countries have since adopted plant variety specific legislation. *Bangladesh* – Plant Varieties Act (1998); *China* – Regulation of the People's Republic of China on the Protection of New Varieties of Plants (1999); *Hong kong* – Plant Varieties Protection Ordinance (1997); *India* – Protection of Plant Varieties and Farmer's Rights Act (2001) Rules (2003) in force: http://agricoop.nic.in/seed/farmersact2001.htm; *Malaysia* – Protection of New Plant Varieties Act (July 2004); *Pakistan* - Plant Breeders' Rights Ordinance (2000, draft); *Philippines* - Plant Variety Protection Act (2002) Implementing Rules & Regulations 2002; *Sri Lanka* - Protection of New Plant Varieties (2001, draft); *Taiwan* - Plant Variety and Seed Law (2002, in force); *Thailand* – Plant Varieties Protection Act (1999 in force); *Vietnam* – Ordinance on Plant Varieties (2004, in force). See http://www.grain.org/brl/tk-brl-en.cfm.

[2] Per Pinstrup-Andersen, "Emerging Issues in Trade and Technology: Implications for South Asia" Indian Council for Research on International Economic Relations (2002), p. 2. The issues of Intellectual Property in Agriculture are crucial to South Asia, because the region has 23 percent of the world population, 44 percent of world poor while the income generated is a mere 2 percent of the world income.

interests of the farmers will be protected who had been in the center of conservation, preservation and development of plant genetic resources (PGRs). In this context the question of protection of traditional knowledge (TK) and rewarding the traditional communities for their TK in PGRs, is an important issue. The environmental and social issues related to the conservation of bio-resources, bio-diversity and food security are the over-riding issues in this context.

While addressing these issues, a proper IP format needs to be adopted to protect plant varieties and biotechnological inventions in the process of meeting with the obligations of the TRIPS, which should be consonant with the sustainable growth of these countries. Since Article 27.3(b) is currently under review,[3] in the WTO negotiations, developing countries must position themselves in review negotiations and frame laws/ policies, keeping in sight these issues. In this regard, the TRIPS' interface with the Convention on Biological Diversity (CBD), which imposes a duty to give access to PGRs and benefit sharing, is of great significance (Art. 15 of the Convention).[4] Its mandate to respect, preserve and maintain TK of indigenous and local communities is to be given effect (Art. 8(j))[5]. Similarly the FAO's International Treaty on Plant Genetic Resources for Food and Agriculture (PGRFA), 2001 has a special relevance for the protection of farmers' rights (Art. 9). The PGRFA Treaty mainly incorporates the philosophy of the CBD but adopts the multilateral approach on access and benefit sharing (ABS) in contrast to the bilateral approach under the CBD. The Bonn Guidelines (May 2002), adopted by the Conference of Parties of the CBD[6] provide a mechanism of access and benefit sharing for genetic resources has relevance in giving effect to CBD mandate on this aspect. In implementing the TRIPS mandate under Article 27(3)(b), the obligations under these international instruments are to be fulfilled in framing an IP system on plant variety protection (PVP), which should have a sustainable development perspective. In this regard, this paper, in particular, examines the issues of R&D in agriculture, traditional knowledge and benefit sharing, and farmers' rights to ensure food security of these countries from the perspective of developing countries while keeping India in context.

[3] Article 27(3)(b) is the single provision in the TRIPS Agreement, which was subjected to an early revision. It is now before the TRIPS Council for revision under the mandate of Doha Declaration. The Doha Ministerial Declaration, in paragraph 19, mandated the TRIPS Council that:
"in pursuing its work programme including under the review of Article 27.3(b), the review of the implementation of the TRIPS Agreement under Article 71.1 ... to examine, *inter alia*, the relationship between the TRIPS Agreement and the Convention on Biological Diversity, the protection of traditional knowledge and folklore, and other relevant new developments raised by members pursuant to Article 71.1. In undertaking this work, the TRIPS Council shall be guided by the objectives and principles set out in Articles 7 and 8 of the TRIPS Agreement and shall take fully into account the development dimension." See WTO-Doha Ministerial 2001: Ministerial Declaration (Nov. 14, 2001) WTO Doc. WT/M! (01) Dec/1,20, Nov. 2001.

[4] The relationship between the TRIPS Agreement and the CBD has become a source of considerable controversy, particularly in the context of access and benefit sharing (ABS) and transfer of technology under Art. 16 of the CBD.

[5] CBD has constituted an open-ended Inter-sessional Working Group on Article 8(j) and related provisions in 1998. See UNEP Doc. UNEP/CBD/COP/7/7, 12 Dec. 2003. At COP-VII, held in Kuala Lumpur on 9-20 Feb. 2004, by decision VII/16, it was decided to hold four regional workshops in Asia, Africa, Latin America and Eastern Europe in 2005 to prepare composite reports on TK on a regional basis for further work on TK. Available at www.biodiv.org/decisions/default.aspx>

[6] COP-VI, Decision VI/24. These guidelines, though voluntary, nevertheless are a significant step towards the harmonization of the regime on ABS, which the countries may incorporate in their laws.

Intellectual Property Rights for Biotechnological Inventions

Article 27(3)(b) excludes plants and animals and essentially biological processes for the production of plants and animals from patentability and makes microorganism and micro-biological and non-biological processes patentable. This provision, however, can be subjected to many approaches in the context of recent development in biotechnology. The various elements of this provision need to be explored. First, unlike European law (Art. 53 (b) of the European Patent Convention, 1973) and other legislations that followed the same approach in according protection to plant varieties, this provision refers to 'plants and animals' and not to a certain classification thereof ('varieties', 'races' or 'species'). In the absence of any distinction and also in the light of the second sentence of the same Article that introduces an exception for one particular classification ('plant varieties') in Art. 27(3)(b) – the exclusion is to be interpreted in broad terms inclusive of animals and plants as such, animal races and animal and plant species.

Second, the exclusion of 'essentially biological processes' is limited by the reference to processes 'other than non-biological and microbiological.' Its aim in the TRIPS context is to limit the exclusion of patentability to traditional breeding methods, while preserving the possibility to obtain protection, for instance, on developments based on cell manipulation or, with the advances in biotechnology, the transfer of genes. According to the TRIPS Agreement, processes employing micro-organisms (such as fermentation) are also patentable, in accordance with current practice in most countries. However, more complex and new is the concept of 'non-biological processes'. How can a plant or an animal be produced by a process, which is not totally or in part biological? This needs clarification.

Third, the obligation to provide effective protection to plant varieties is another important basis for the expansion of the scope of intellectual property in the field of biotechnology in which most of the developing countries do not have the capacity to benefit from it and constitutes one of the relatively few exceptions to patentability in the TRIPS Agreement. Although there is a flexibility as regards the form of protection, but all WTO members would be bound to protect plant varieties in one form or the other, which should be effective. Plant varieties produced by traditional means of breeding and screening techniques, from uncontrolled events (for example, mutation) and cross-fertilisation to rDNA technology using tissue cells, as well as microorganisms, will become the subject matter of patent protection or a *sui generis* system.

It is also notable that while excluding plants and animals from patentability, will this exclusion extends to the parts thereto as well?[7] Will the "part thereof" include, for example, proteins and genes on the basis that the living body essentially comprises proteins, genes, etc.? Many types of biological inventions are likely to involve the use of microbiological processes and microorganisms. These cannot be excluded under Article 27(3)(b) as presently framed. Further, could the bar on patents for animals, plants and essentially biological processes be made compulsory and extended to microorganisms and traditional knowledge as well? Industrialized countries at the cutting edge of biotechnology naturally desire to strengthen the protection further. But developing countries first need to determine to what extent and how they wish to harness biotechnology for their economic development under IPR regime, since rDNA (recombinant deoxyribonucleic acid) technology has great potential in creating new plant varieties and meet their health-care needs. Except few threshold countries, like Brazil, China, Cuba and India, most of these countries lack required capabilities to harness its benefits. Moreover, compared to health

[7] The Patents (Amendment) Act, 2002 (India) excludes "plants and animals in whole or any part thereof" other than micro-organisms but including seeds, varieties and species and essentially biological processes for production or propagation of plants and animals" (sec. 3(j)).

biotechnology in developed countries, it is agro-biotechnology that has got priority in these countries and health-related biotechnology is beyond the reach of most of these countries. These countries, while giving effect to its TRIPS obligations should make provisions to enable them to harness the benefits/potentials of biotechnology for increased production of food and poverty alleviation and addressing the problem of health-care, but also protecting against its ill-effects on environment, including the risks posed by genetically-modified organisms (GMOs).

As Article 27(3)(b) demands that microorganisms, non-biological and microbiological processes be treated as patentable subject matter, but it fails to define these terms. Developing countries can interpret these terms to suit their development goals, while meeting the over-all criterion of patentability as laid down in Article 27.1. Even the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure, 1977 does not define the term "microorganism" and WTO members may adopt a scientific definition of microorganism, covering viruses, algae, bacteria, fungs and protozoa.[8] Members may give it a restrictive definition and even under Article 27(1) can exclude it from patentability by not considering it as invention. The issue of patentability of microorganisms, non-biological material and micro-biological processes thus requires a clear understanding among member countries of the TRIPS, which presently does not expressly include or exclude naturally occurring substances, such as genes and cells, from patent protection.[9] But clearly if they verge on discovery, they may be excluded from protection,[10] and nothing obliges WTO members to follow an expansive approach in respect of patenting of substances existing in nature, such as genes, cells or plants as such.

Under the US law (35 USC 100 (a)), the term invention is defined as meaning both "invention" as well as "discovery". But in reality, the US Supreme Court decision in *Diamond v. Chakrabarty*[11] has clarified that the claim should be a product of human ingenuity to be patentable which means that products found in nature as such are not patentable. TRIPS also does not mention whether or not genes should be patentable, whether derived from plants, humans or animals. The issue relevant here is what constitutes an innovation in relation to genetic material. Can it be protectable in its natural format (as discovery) or isolating and purifying it would make it patentable. The issue can be addressed in the national legislation.[12] In addition, patents are widely used to protect technologies used in plant genomes (related to mapping, sequencing and analyzing genomes). This may again be subjected to national legislation.

---

[8] See George Wei "Fitting Biological Products Within the Intellectual Property Framework: Challenges Facing the Policy Makers", paper presented at Intellectual Property and Biological Resources Conference, December 2003, Singapore, p. 11. The European Patent Office includes within the ambit of 'microorganism', not only bacteria and yeasts, but also fungi, algae, protozoa and human, animal and plant cells. Plasmids and viruses are also considered to fall under this definition.

[9] TRIPS similarly does not make any reference to genes or DNA sequences. While the complementary DNA (cDNA) may be considered as patentable subject matter, it may be refused patent for not being innovative enough since the technique employed has become routine.

[10] Graham Dutifield, "Protecting Traditional Knowledge and Folklore: A Review of Progress in Diplomacy and Policy Formulation", p. 29, UNCTAD/ICTSD draft paper (October 2002) http://www.ictsd.org/iprsonline/unctadictsd/docs/Dutfield/2002.pdf

[11] *In re Diamond v. Chakraborty,* 206 USPQ 193 (1980).

[12] [India's] Patents (Amendment) Act, 2002 does not address this issue. Section 3 excludes from patentability "discovery of any living thing or non-living substance occurring in nature" and section 5 makes bio-chemical, bio-technological and micro-biological processes as patentable.

The TRIPS Agreement similarly does not define "invention" though it lays down a general criterion of patentability in Art. 27(1), i.e., to be patentable an invention should be new, involve an inventive step and be capable of industrial application. Hence, the views differ on patentable subject matter. It is argued that the TRIPS Agreement only specifies the *requirements* that an invention must meet in order to be patentable but it does not provide a definition of what an invention is. This leaves WTO member countries free to determine what should be deemed an invention.[13] Moreover, TRIPS does not contain rules on the modalities and interpretation of patent claims, which are essential to establish the scope of protection. This leaves a substantial leverage with developing countries to give effect to this provision. The exclusions from patentablity, permitted under Article 27(2)[14] of TRIPS could further strengthen this position.[15]
It is, however, notable that despite the express exclusion of plants, animals and biological processes from patentability, the recent trend in bilateral agreements between developed and developing countries is specifically to cover biotech inventions without any exception, and the bilateral agreements concluded by the United States do not have any specific exclusion for plants and animals from patent law. [16]

The Impact of Plant Variety Protection

Plant variety protection (PVP) can have a narrow and broad meaning. The narrow view only considers plant variety protection from the point of view of commercial breeders and the needs of the biotechnology industry. The protection is considered as an incentive for commercial breeders of plant varieties to invest in R&D. Their increased investment would help in developing new varieties with high yields. The broad view acknowledges that there are different actors in plant variety management who deserve protection and who perform different functions, ranging from innovation (new seeds) to agro-biodiversity management and food security of the nation. They have different implications for developed and developing countries. The broad view can augur sustainable development of developing countries.

The aim of plant variety protection is to provide incentives to breeders to create new varieties by increased investment, which could lead to an increase in yields. On the other hand, there are farmers, most of whom are resource poor and have traditionally replanted, exchanged or sold seed

[13] Carlos M.Correa, "Access to Plant Genetic Material and Intellectual Property Rights" in *Perspectives on Intellectual Property: IP in Biodiversity and Agriculture*, 117-118 (2001, Sweet & Maxwell).
[14] Art. 27(2) provides that: "Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect order public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by domestic law."
[15] In an ongoing review of Article 27(3)(b), developing countries members have submitted their proposals to exclude life forms from patentability. See principally the submissions by the African Group, WTO Doc. WT/GC/W/362, 12 Oct. 1999; IP/C/W/404, 26 June 2003; submissions by Brazil, China, Cuba, the Dominican Republic, Ecuador, India, Pakistan, Peru, Thailand Venezuela, Zambia and Zimbabwe, WTO Doc. IP/C/W/356, Doc. IP/C/W/403, Doc. IP/C/W/420; India's submission, WTO Doc. IP/C/W/370, 8 Aug. 2002.
[16] See for example, EU agreements with ACP countries (2000), Morocco (2000), Palestine Authority (1997), South Africa (1999), Tunisia (1998), Bangladesh (2001), Mexico (2000), insisting on either to patent bio-tech inventions, or join UPOV Convention on plant variety protection; US concluded agreements with Cambodia (1996), Mongolia (1991), Jordon (2000), Vietnam (2000); Ecuador (2000), Nicaragua (1998), Trinidad and Tobago (1994), Singapore (2003), Bahrain (29 May 2004); and US and Canada with Mexico (1994). See Intellectual *Property Rights and Development* – Policy Discussion Paper, UNCTAD/ICTSD (Nov. 20, 2001) pp. 58-60.

from the previous year's crop, in which case breeders would have difficulty in recouping the investments made in improved varieties through repeat sales. Patents or PBRs normally impose restrictions on farmers' ability to sell seeds grown on their one land (and in some cases to reuse it) and thus enhance the market for the breeders' seed. Even in the developed countries, reuse of seeds remains quite common although for many crops annual purchase is now the rule. In developing countries the majority of farmers reuse, exchange or sell informally to neighbours, and annual purchase of new seed is relatively rare in most countries. Any mechanism of plant variety protection should protect and encourage the contribution of farmers to conservation and innovation of their varieties, which are part of their traditional knowledge, by a process of selection and experimentation.

Looking into the Indian seed sector, only 20% of seed demand is met by the formal sector, which includes government agencies, private seed companies, cooperative societies and other registered participants, and 80% by the informal sector, not under the control of official monitoring bodies. Farmers are big players in it. To sustain the agriculture in these countries, farmers' rights are to be treated as ownership rights over PGRs which will not only help in poverty alleviation but would also help in biodiversity conservation.

It is also important to note that TNCs are the big players in the seed sector in the world economy. There is no mechanism to protect the innovations of farming communities and to compensate them if any new variety fails to germinate, or it is not eco-friendly or it is hazardous to health. As seeds are the first link in the food chain, through control over seed sector, TNCs can control the food system and may thus affect the food security of a country.[17] Farmers fear for high prices of seeds and less control over their harvest. It is also notable that PBRs may contribute to a trend whereby traditionally diverse agro-ecosystem, with a wide range of traditional varieties may be replaced by few varieties with significant commercial potential, with the result that the range of nutritious foods available in local markets would become narrower. It will also lead to more reliance on cash crops than food crops, affecting the sustainability of the bio-resources and ultimately the food security of the country. Monocultures of single agrochemical-dependent varieties, which are more vulnerable to natural forces and plant diseases, may lead to genetic erosion and reduction in biodiversity. Since biotech industry is profit-driven (private players), they focus on producing commercially trans-genic crops and not on the staple food. This will adversely affect the resource-poor farmers to meet their nutritional needs.

It is further notable that hybrid seeds produced either by the traditional technology of breeding, cross-fertilizations, backcrossing, or by the rDNA technology of using tissue cells or micro-organisms, are more expensive than reproductively stable non-hybrid seeds and with a limited life span of one cropping season (ranging from three months to one year, depending on the species). Consequently, the hybrid seeds confer a natural form of protection by which seed companies can more readily capture a return on their investment, as farmers must buy fresh seed for each planting season. These seeds are conditioned to certain patented agriculture inputs like bio-fertilizers and bio-pesticides, which together tend to turn agriculture into a capital-intensive industry, and may wipe out the small and marginal farmers. The introduction of genetic use

[17] It has been stated that if all farmers in India, who are the original breeders of the plant varieties (or propagating material) are forced out of the market, the seed industry will have a 7.5 billion dollar market every year. See Vandana Shiva, "Bio-diversity Totalitarianism: IPRs as Seed Monopolies" Eco. & Pol. Weekly 2582 (Oct. 11, 1997).

restriction technology (GURT) may further be detrimental to farmers' rights.[18] The "terminator" technology would render the seed sterile so that it is physically not possible to grow a second crop, while at the same time controlling its other characteristics. The effect of this technology is self-enforcing bringing to an end to farmers' rights. This technology is cheaper and at the same time self-enforcing.[19]

This scenario will have its social costs in developing countries where most of the farmers are resource poor with small land holdings. The developing countries' efforts should be geared to offset these social costs and ensure access for farmers to good quality seeds at reasonable prices, although at the same time structural reforms in the agricultural sector should also be introduced, beside putting in place measures to keep under check the prices of seeds/propagating material. But a holistic approach may be adopted under a proper *sui generis* legislation on plant variety.[20]

One *sui generis* model of plant variety protection, followed in developed world is provided under the UPOV Convention, 1961. The several revisions of UPOV since its signing in 1961 have led to a progressive strengthening of plant breeders' rights.[21] The 1991 Act of the UPOV Convention is closer to the patent law, even though the scope of the protection is not equivalent to patent protection. It is wider in its extent as to breeders' rights and limited as to farmers' privileges compared to 1978 Act. To be eligible for protection, the plant variety must be novel, distinct, stable, and uniform (in UPOV 1991) or homogenous (in UPOV 1978), whereas farmers' varieties are diverse and heterogeneous in nature. But the plant variety protection under the patent law or *sui generis* system, as outlined in the UPOV Convention, is most suitable to developed economies where the farmers use standard modern technologies, including power-driven machinery and vehicles and a range of chemicals.[22] New varieties are produced in accordance with new technologies. TRIPS does not stipulate that members should adopt the UPOV model for their *sui generis* system and does not refer to UPOV in the text, but it also does not give the choice to the countries to have a non-monopolistic model of protection of plant varieties. The

[18] 29(3) of the [India] Protection of Plant Varieties and Farmers' Rights Act, 2001 in Sec. 29(3) states: "… no variety of any genera or species, which involves any technology including which is injurious to the life or health of human beings, animals or plants shall be registered under this Act. Explanation – For the purpose of the sub-section, the expression 'any technology' includes genetic use restriction technology and terminator technology."

[19] It has not been put to use so far in any country.

[20] In the Indian context, agriculture needs a large-scale government support in the areas of research infrastructure, front-line extension, water and land management, post-harvest management, rural credit and agricultural risk management. See Sudhir Kochhar "R&D in agriculture in context of WTO-TRIPS" 3 (paper presented at UPCAR, Lucknow (5 July, 2002).

[21] Union Internationale pour la Protection des Obtentions Vegetales/ International Union for the Protection of New Varieties of Plants (UPOV) presently has 56 members. The Convention since its coming into force in 1968 was amended in 1972, 1978 and 1991. The 1991 Act came into force in April 1999.

[22] But there also, it is not without problems. For example, it was predicted way back in 1986, by the US Congressional Office of Technology Assessment on biotechnology, entitled 'Technology, Public Policy and the Changing Structure of American Agriculture', that by the year 2000, about 50,000 large firms will account of 75 per cent of the US agricultural production and adds that biotechnology will quicken the rate of farm failures unless the US restructures its policy to help the medium and small farmers, See, 'OTA report foresees mixed future for farmers', McGraw-Hill, Biotechnology Newswatach, Vol. 6, No. 8(21 April 1986), at 2.

system has to be effective. The developed countries, in their bilateral agreements with developing countries are already insisting on UPOV model.[23]

Research and Development in Agriculture

Research in the evolution of new plant varieties has a close interface with biodiversity. Plant breeding research has always endeavoured to evolve varieties through the techniques, for example, selection, backcrossing, etc. with desirable characteristics, namely, high-yielding, photoperiod sensitivity and dwarfism. This involves the use of biological material, particularly germplams. With recent advances in biotechnology, it is now possible to isolate desirable genes from some plants and transmit the same through rDNA technology[24] into a targeted plant and a new variety is created. As biological materials are products of biodiversity, there is an intimate relationship between biotechnology and biodiversity, which has implications for intellectual property rights. Thus, biodiversity is another important aspect, which has to be taken into account while undertaking any exercise on plant variety legislation.

The genetically modified (GM) crops, developed by using input traits (eg. resistance to insect pests and plants diseases), output traits (eg. delayed fruit ripening, better taste, elimination of saturated fats in cooking oils, elimination of allergens, better delivery of necessary nutrients), agronomic traits (eg. resistance to drought, salinity, acidity, flood, etc. and increase in crop yield) of nitrogen fixation have also been made possible by rDNA technology. The new seed products with induced traits are providing agronomic benefits such as disease resistance, pest resistance, herbicide tolerance, and also extended shelf life of harvested produce. Genetic engineering has rendered the transfer of genes across sexual barriers possible and has thus enhanced the economic value of biodiversity for countries whose economies are based on agriculture. But the benefits of this technology can be reaped only with assured irrigation mechanism in a country concerned.[25]

R&D in biotechnology is principally confined in developed countries, particularly in private hands. It is estimated that about 6.5% of all genetic research undertaken in agriculture is focused upon germplasm derived from wild species and land races from developing countries. In most of the developing countries, R&D is concentrated in the public sector viz., government agencies, universities and research institutions and despite being given incentives to the private sector, no perceptible change has been registered in this trend. [26]

---

[23] See *op cit* 16. The purpose of the UPOV Convention is to ensure that the member States of the Union acknowledge the achievements of breeders of new plant varieties, by making available to them exclusive property right, on the basis of a set of uniform and clearly defined principles. Through its successive revisions, the scope and length of protection has been extended. The minimum period of protection has been increased to 20 years (25 years for vines and trees) in the 1991 version (from 15 and 20 under 1978 Act).

[24] rDNA technology modifies the genetic code of living organism, i.e., microorganisms, plants and animals and by so doing, new species of plants and animals are created. The end result is a genetically modified or manipulated organism (GMO). This process is much more advanced and faster than the traditional techniques of breeding plants and animals, see M. Roberts, "A Consumer View of Biotechnology", 4 *Consumer Policy Review* 99 (April 1994).

[25] See CIPR Report, *Integrating Intellectual Property Rights and Development Policy*, p. 58 (Sept. 2002).

[26] See New Policy on Seed Development, 1988 (India). Despite giving incentives, the foreign seed companies were not willing to part with the parent lines/breeder or nucleus after two years, as required. They would only part with their know how or propagating material for plant breeding to their own subsidiaries in India but not to Indian companies without agreements protecting confidential information. It is often being argued that the New Seed Policy would lead to a high dependency on foreign technology

Globally, however, agriculture is better served by the private sector compared to health research in developing countries. It is estimated that globally about one-third of all agricultural R&D is spent in developing countries in mark contrast to the maximum of 5% for health research in developing countries.[27] The global seed companies may, nevertheless, be attracted to crops that are widely grown in developing countries, with assured returns. Seed production is undoubtedly a highly remunerative enterprise and its remunerative nature indeed works as an attractive proposition for farmers to participate more and more in this sector. On the other hand, quality seed production is quite a sophisticated, time-consuming proposition and also involves capital-intensive technology particularly the seed production process needed for the new HYVs. Hybrids require an effective specialized seed production system, which is beyond the reach of most of the farmers in developing countries. [28]

By according IP protection to plant varieties, the question one may have to ask that whether it will increase R&D in agriculture specific to developing countries and whether there will be any movement in transfer of technology related to the agricultural needs of these countries. It is also necessary to enquire whether patents or a *sui generis* regime will better address the concerns of developing countries. The studies in the United States have revealed that there is no credible evidence to suggest that R&D activity has increased because of the introduction of plant variety protection, unless the product is in demand,[29] neither there is an evidence to support that the IP protection has led to increased investment in this sector. On the contrary IP protection has contributed to a large number of mergers that took place in the seed industry. It has been mainly used as a marketing tool for product differentiation and to ward off competition. A recent study found that PVP on wheat in the US had not contributed to increased investment in private sector wheat breeding, but may have done so in the public sector. Nor had it contributed to an increase in yields. But the share of wheat acreage sown to private varieties had increased markedly, reinforcing the suggestion that the main impact of PVP has been as a marketing tool.[30] The PVP, even though has facilitated the access to foreign genetic material, but in most of the time it comes with restriction on sale, distribution, exports etc. The new IP regime enables the right-holder to have a firm grip over its technology with no incentive to transfer to developing countries. This scenario so far has benefited the commercial farmers and seed company with very little for the small farmers to look at, and on the contrary they may be deprived of their traditional rights of seed saving and exchange under a PVP system.

---

and imported seeds will undermine the development of local R&D. This is thus a national issue, significant for the food security of the country.

[27] See CIPR Report, at p. 60. See also Commission on Macro economics and Health (2001) WHO, Geneva, http://www.\3.who.int/whosis/cmh/cmh-report/e/report.cfm?path=cmh,cmh-report&language=english. Globally, private sector (mainly TNCs) is the big player in this, who for their R&D, fall back on the genetic resources provided by developing countries.

[28] In India, the Indian Council of Agricultural Research (ICAR), the Indian Agricultural Research Institute (IARI) are in the forefront in the development, production and distribution of seeds. Despite the New Seed Policy declared by India in 1988 to attract the private sector investment and involvement in agriculture R&D, there has not been any movement in this direction.

[29] Butler L.&Marion, B. "*The Impacts of Patent Protection on the US Seed Industry and Public Plant Breeding*", Food Systems Research Group Monograph 16, University of Wisconsin (2001).

[30] Alston, J.& Venner, R. "*The Effects of the US Plant Variety Protection Act on Wheat Genetic Improvement*", EPTD Discussion Paper No. 62, International Food Policy Research Institute, Washington, cited by CIPR Report, at p. 61.

There are also evidence that IPRs, whether patents or PBRs, in agriculture, have played a significant role in major consolidation of global seed and agricultural input industries. This consolidation has taken place at vertical and horizontal levels, though driven by technological changes, and has now maximized the control of seed industry on distribution channels also. These companies indulge in anti-competitive practices by better control over seeds and agricultural inputs (pesticides, fertilizers etc.), through cross-licensing, strategic alliances.[31] This also impacts the prices and access to these agricultural tools. Licensing of their technology is generally riddled with restrictive clauses. With the increased protection in agriculture, it is feared that R&D in agricultural biotechnology will slip into private hands, impacting adversely thereby the access to this technology and further research in the IP protected area, which will be then more guided.

This increasing trend towards concentration of power in big seed companies is a serious competition issue, which may very well affect the food security of developing countries, if the propagating material, other agricultural inputs and related technologies are over-priced, and thus making them out of the reach of poor/small farmers. The developing countries need to address this issue by putting in place a competition law.[32]

The availability of genetic resources for further research to develop new varieties is also an issue to be addressed in a PVP regime. The patents for plant varieties provides a stronger form of IP protection, by limiting the rights of farmers over propagating material/seeds, and also limit the right of a breeder to use protected variety for further research for breeding purposes. Plant-related biotechnological inventions are likely to be protected not only by a single patent but also in many cases by several patents. Moreover, patents may cover not just a plant but also genes and DNA sequences (which otherwise may not be patentable). Patent protection is also frequently obtained through broad patent claims, for example, on genes, the vector or carrier for effecting the transformation, which may cover a number of potential varieties or crops incorporating the gene. This may seriously hinder further R&D as it may in effect amount to as patenting the whole plant, because the patent normally extends to "all material… in which the product is incorporated."[33] As a patented product, this will make the genetic resources as inaccessible, which may be dealt by a well-crafted exception in the patent law. Under a *sui generis* regime, it is easy to craft an exception. Furthermore, to prove that a new variety meets the criteria of patentability is more difficult and costly than obtaining plant variety protection, where the criteria for protection are lower. The PVP, however, may provide less protection than patents and may provide little incentive for research, but correspondingly would be less restrictive of incremental follow-on innovation than patents. As the patents are the strongest form of intellectual property protection in the sense that they normally exact the greatest control over the patented genetic material, any far reaching exceptions for research and farmers' right may be difficult to create, which will be possible through a PVP law.

There is also the potential for agricultural technologies developed by the private sector to spill over to the benefit of the commercial sectors in developing countries at the cost of poor farmers. To safeguard their interests, more public sector research specifically oriented to such farmers is required. Privatization of agricultural research, the increased concentration of ownership of

[31] See, for instance, two recent agreements announced on 2/3 April 2002, between Monsanto and DuPont, and Monsanto and Ceres. Source : http://www.monsanto.com/monsanto/media/02/default.htm.
[32] The Indian Competition Act, 2002, does not address this issue squarely, though it is focused on curbing monopolies to promote competition. See sections 3, 4 and 5 of the Act.
[33] See EU Biotechnology Directive, Directive 98/44, Articles 9 (and also Article 8).

breeding material, research tools and technologies in the small number of TNCs would be detrimental to food security of the country and government's efforts to alleviate poverty. Private sector does not find enough incentives for research relevant for poor regions and poor farmers.[34] Governments can control and motivate the public institutions to undertake country-specific research more easily than the private sector.

There is also the problem of genetically modified crops, in which the development of genetic traits such as herbicide tolerance is determined principally by search for commercial advantages, rather than the environment or land specific requirements of a country or their impact on human and animal health, and on poor farmers if they lead to adverse results. They can be introduced in these countries only after addressing these concerns and undergoing a regulatory procedure of field trial and appropriate approval of designated authorities. In India in recent years, the introduction of Bt Cotton (GM crop) has generated fair amount of controversy in the country despite its being granted conditional sanction from the Genetic Engineering Approval Committee (GEAC) of the Department of Biotechnology (DBT) on March 26, 2002 to Monsanto-Mahyco Biotech Ltd. of the USA for commercial cultivation. A case is pending before the Supreme Court of India[35] filed by the Research Foundation for Science, Technology and Ecology challenging the 1998 field trials of Bt Cotton, pointing irregularities and violations of bio- safety laws and guidelines, and susceptibility of crop to pests and diseases.[36] Similarly, ICAR claims that Bt Cotton developed by it is cheaper and superior to Monsanto cotton because it contains multiple pest resistant genes. High price of GM seeds is another issue.

Traditional Knowledge

The protection of traditional knowledge, innovations and practices (hereinafter referred to as TK) of indigenous communities has become a big issue in the context of protection of plant varieties through an effective intellectual property right regime. The Convention on Biological Diversity (CBD) 1992 under its Article 8(j), along with Articles 15 and 16, has brought the issue of relationship between CBD and TRIPS Agreement to the centre-stage in the context of biotechnological inventions and plant variety protection. The main issue in this context is the harmonization of TK protection with IP law while granting patents or plant variety protection on plant genetic resources (PGRs). Many instances of bio-piracy/ misappropriation of PGRs have made TK a priority agenda of developing countries. In many of these cases of biopiracy, claims in the patents on plants and their genetic resources are not fundamentally different from the practices applied by the traditional communities in the utilization of these plants as food, cosmetics or traditional medicines. Traditional knowledge associated with a biological resource is an intangible component of the resource itself. TK has the potential of being translated into commercial benefits by providing valuable leads for the development of useful products and processes. The potential of TK for the growth and development of pharmaceutical and biotechnological- based industries has been widely reported.[37] Its potential in the growth of new plant varieties with selected traits is well-established.

---

[34] CIPR Report, p. 64.

[35] *Research Foundation for Science, Technology & ecology v. Union of India & Ors.*, Supreme Court of India, Writ Petition (Civil) No. 71/1999.

[36] In 1989, Government of India issued Rules for the Manufacture, Use, Import Export and Storage of Hazardous Microorganisms Genetically Engineered Organisms or Cells, framed under sections 6 and 8 of the Environment Protection Act, 1986, on Dec. 5, 1989. To date, this is India's biosafety law; it has signed the Cartagena Protocol on Biosafety on Jan. 23, 2001.

[37] It is stated that natural product-derived pharmaceutical alone contributed an estimated $ 120 billion, or 40% of global pharmaceutical sales in 1997, with global trade in raw botanical materials approximating $ 8

Due to the sustained insistence of developing countries, which own about 80 percent of the world's biodiversity and indigenous/local communities of these countries are principal holders of TK in PGRs, the protection and preservation of TK has come on the agenda of a number of inter-governmental bodies. The most notable work is going on under the WTO/TRIPS Council in the context of Article 27(3)(b), WIPO and UNED/CBD.

The WIPO's General Assembly established an Inter-Governmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (hereinafter referred to as IGC) in 2000 with the mandate to discuss IP issues that arise in the context of (i) access to genetic resources and benefit-sharing, (ii) protection of TK, whether or not associated with these resources, and (iii) protection of expressions of folklore.[38] The IGC has so far held seven sessions (the last was held on Nov., 1-5, 2004) and has prepared an impressive number of documents,[39] including the model clauses for genetic resources contracts,[40] a toolkit for documentation of TK protection,[41] and work on elements of a possible *sui generis* system.[42]

While informative and technically solid, the analysis undertaken by the WIPO Secretariat for the IGC has attempted to explain traditional and indigenous practices of conservation and transmission of knowledge under established IP concepts. The IGC has centered its activities mainly on solutions that tend to minimize the rigours of IP criteria. The IP solution is sought for TK in the public domain, which is a small part of the vast arena of TK that has strong moorings in cultures and traditions/rituals, etc.[43] WIPO's efforts are aimed at the possible development of a *sui generis* regime for TK. The recognition and enforcement of customary law as a form of protection that respects cultural diversity, has been largely overlooked. Its main emphasis is on the economic aspects of TK, if it is put to commercial use, and not on its further diffusion, preservation and protection; the aspect of management of TK has been totally ignored. The extent to which WIPO's approach to the protection of TK would serve the interests of its intended beneficiaries, which will possibly be identified under national law, needs further examination, along with the cost-aspect in putting such a system in place.[44] The IGC's work further requires looking into the novelty criterion applied in different jurisdictions in respect of TK in the public

---

billion in the same year, see S.A.Laird and K. ten Kate, **The Commercial Use of Biodiversity: Access to Genetic Resources and Benefit Sharing,** 78-79(1999). See also P. Principe, "Economics and Medicinal Plants", in T.R. Tomlinson and O. Olayiwola Akerela (eds), **Medicinal Plants: Their Role in Health and Biodiversity** (1998, University of Pennsylvania Press, Philadelphia). A great deal of TK is likely to have cultural or spiritual value that cannot be quantified in any monetary terms. See D.A.Posey (ed**), Cultural and Spiritual Values of Biodiversity** (1999, UNDP and Intermediate Technology Publications, Nairobi & London).

[38] See WIPO Doc. WO/GA/26/6, Aug. 25, 2000, p. 5.

[39] See http://www.int/tk/en/igc/documents/issues.html for the list of documents prepared by the IGC. See also WIPO Doc. WIPO/GRTKF/IC/5/12, April 3, 2003.

[40] WIPO Documents: WIPO/GRTKF/IC/4/10, March 25, 2002; WIPO/GRTKF/IC/3/4, May 17, 2002; WIPO/GRTKF/IC/2/3, September 10, 2001.

[41] WIPO Document: WIPO/GRTKF/IC/4/5, Oct. 20, 2002.

[42] WIPO Documents: WIPO/GRTKF/IC/5/3, May 2, 2003; WIPO/GRTKF/IC/4/8, Sep. 30, 2002; WIPO/GRTKF/IC/3/8, March 29, 2002.

[43] For more details on the work undertaken by different inter-governmental agencies, see S. K.Verma, "Protecting Traditional Knowledge – Is a *Sui Generis* System an Answer?" 7 JWIP 765 (Nov. 2004).

[44] See Carlos M. Correa, "Recent International Developments in the Area of Intellectual Property Rights" ICTSD/UNCTAD Dialogue, 2nd Belligo Series, 18-21 Sept., 2003 p. 8 http://www/iprsonline.org/unctadictsd/dialogue.

domain as prior art and allowing the patenting of genetic resources and TK. For example, in the USA undocumented foreign knowledge or inventions disclosed in non-written form or oral outside the country is eligible for patents[45].

Beyond the IGC's work, however, the WIPO is also undertaking steps to enhance the coverage of documented TK in the minimum documentation of the Patent Cooperation Treaty (PCT)[46] and to expand the International Patent Classification (IPC) to contain categories for TK subject-matter to provide for more accurate and focused searching for relevant TK during the patent examination process.[47]

The discussions on TK at other international fora are also proceeding on the lines of IGC, though developing countries are more persistent in TRIPS Council, which led to its inclusion in the Doha Round (paras19 and 32). Before the TRIPS Council, the matter was raised in the context of review of Article 27(3)(b) in 1999. The proposals from developing countries desired a composite review of the Article, including TK related to PGRs, and together they argue that the exclusions in Article 27(3)(b) should be clarified. The life forms should be excluded from patentability, the information relating to the origins of a biological invention become a part of the patent application process and that the principle of prior informed consent under the CBD, should be incorporated into TRIPS.[48] They view that while adopting a *sui generis* system, countries can provide provisions to this effect. There are also heightened concerns about the grant of patents and/or other IPRs covering TK by developed countries to persons other than the indigenous peoples/communities, without their authorization and without sharing benefits with them that accrue from such use.

The developing countries, do not find the present IP regime adequate to address their concerns in relation to TK. They are insisting that the TRIPS Agreement should be suitably amended or provide mechanism requiring that an applicant for a patent on biological material or TK should, as a condition to acquire patent rights, (a) disclose the source and country of origin of the biological resources and of the traditional knowledge used in the invention; (b) provide evidence of prior informed consent through approval of authorities, and (c) provide proof of adherence with the benefit-sharing laws of the source country.[49] Thus, the developing countries' main emphasis, at international fora, has now more focused on biopiracy/ misappropriation of TK and benefit sharing.

Developing countries have also raised the issue of disclosure of the origin of GRs and TK before the ongoing negotiations under the WIPO on the Substantive Patent Law Treaty. Developed countries, however, have urged that the Standing Committee on the Law of Patents (SCP) should

---

[45] Contrary to US Practice, Indian Patents (Amendment) Act 2002, makes an invention unpatentable if based on traditional knowledge, oral or otherwise. See section 3(p) read with section 25(k).

[46] See WIPO Doc. PCT/CTC/20/5; PCT/MIA/7/3; and PCT/MIA/7/5; see also WIPO Doc. WIPO/GRTKF/IC/6/6, 30 November 2003, p. 12.

[47] The Committee of Experts of the Special Union for IPC has already started the process; see WIPO Doc. IPC/CE/32/12; WIPO Doc. WIPO/GRTKF/IC/6/6, 30 November 2003.

[48] For a detailed summary of the various proposals, see Table 1 in Carlos M. Correa, *Traditional Knowledge and Intellectual Property,* Discussion Paper, Qaker United Nations Office, Geneva 2001, 24-25; see also S.K.Verma, *op. cit.* 44, at 779 *et. seq.*

[49] See *The Protection of Traditional Knowledge and Folklore : Summary of Issues Raised and Points Made,* WTO Doc. IP/C/W/370, 8 Aug. 2002. The developing countries have submitted a checklist of issues which need to be addressed in giving effect to these requirements: see WTO Doc. IP/C/W/420, 2 March 2004. See also India's submission, WTO Doc. IP/C/W/198, 14 July 2000, and India's presentation at the International Seminar on Systems of Protection of Traditional Knowledge, organized jointly by UNCTAF and Government of India, 3-5 April, 2002, New Delhi, pp.3-4.

not tackle this issue until the IGC finishes reviewing the matter of TK.[50] Developed countries do not support the revision of Art. 27(3)(b) and want debate over CBD and TK and its interface with IP outside the TRIPS purview and into the WIPO. They are of the view that TK can be best protected through: (a) bilateral contracts between the users and providers of genetic resources; and (b) databases and registers on TK to be used by the patent offices in cases of biotechnological inventions.[51] But this does not address the issue of consequences of non-compliance with the national legislation and the IPRs granted on genetic resources and TK. In order to assist the Council to discharge its Doha mandate on Article 27(3)(b) different nations/national groups have made submissions,[52] which highlight the contrasting approach on the issue of protection of TK under the TRIPS Agreement between the industrialized and developing countries.

But a *sui generis* system for TK protection at international level, desired by developing countries, is nowhere in sight and its conclusion in the near future is a far-away possibility. At the national/regional level also, attempts are underway to protect TK and presently at least 22 countries and five regional groupings had made or in the process of making available a *sui generis* form of legal protection for TK-related subject-matter as a part of plant variety protection or as an independent comprehensive TK-legislation.[53] These national/ regional regimes suggest a great diversity in approaches, scope, and types of rights and modes of implementation and they do not endorse the "one-size-fits-all" approach towards TK protection at the international level. It is required that the subject matter eligible for TK protection be precisely defined, stakeholders should be identified and a viable enforcement mechanism should be devised at national/international levels.At the international level, apart from the two instruments of worth mentioning, the Bonn Guidelines on Access and Benefit Sharing[54] and the FAO's International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA),[55] no international instrument has been readied for the protection of TK, addressing its holistic character.

In the meantime, failing any agreement on the issues of disclosure and benefit sharing, some countries have already incorporated provisions under their national laws to this effect (e.g. Brazil. Costa Rica, India, Andean Community), making the disclosure requirement as a condition for granting patents for inventions on biological resources. Under the Indian Patents (Amendment) Act, 2002, failing to disclose the source of TK and bio-resource in the patent application for biological invention would be a ground for refusal/ termination of the patent.[56] But the question may be asked whether such a national requirement be subjected to the dispute settlement

---

[50] See the WIPO Website at www.wipo.int/patent/law/en/scp.htm.

[51]WTO Doc. IP/C/W/370, *o*p. cit. 50, paras 9,10 and 27; see also US Communication to the TRIPS Council, WTO Doc. IP/C/W/257, 13 June 2001.

[52] See principally the submissions of African Group. WTO Doc. IP/C/W/404, 26 June 2003; submission by Brazil, China, Cuba, the Dominican Republic, Ecuador, India, Pakistan, Peru, Thailand, Venezuela, Zambia and Zimbabwe, Doc. IP/C/W/356; IP/C/W/403, 24 June 2003 by Bolivia, Brazil, Cuba, Dominican Republic, Ecuador, India, Peru, Thailand, Venezuela, IP/C/W/420, 2 March 2004 by Brazil, Cuba, Ecuador, India, Peru, Thailand and Venezuela; EU Concept paper IP/C/W/383, 17 Oct. 2002; US submissions, IP/C/W/257, 13 June 2001 and IP/C/W/393, 28 Jan. 2003; Switzerland, IP/C/W/400, 28 May 2003.

[53] See *Review of Existing Intellectual Property Protection of Traditional Knowledge*, WIPO Doc. WIPO/GRTKF/IC/3/7. 6 May 2002, pp. 6 *et. seq; WTO Doc. IP/C/W/370, op. cit.*50, p. 7; S.K.Verma, *op. cit. 44*, p 792 *et. seq*

[54] COP-VI Decision VI/24, Access and Benefit Sharing as related to genetic resources.

[55] The Treaty has entered into force on 29 June 2004.

[56] Section 64(p) and (q).

mechanism of the WTO, particularly when the very term "invention" is subject to different approaches.[57]

In any attempt to accommodate the demands of developing countries requires a re-look of Article 29 of the TRIPS and a possible amendment. The provision in Article 27(3)(b) for a *sui generis* system to protect plants varieties might provide a possible way for such a right to be created and recognized under the WTO/TRIPS. A *sui generis* system can be tailored so as to recognize communally held and administered rights that are long lasting and which are supported internationally.[58] TRIPS also sets out minimum standards and does not prevent Members from increasing the rights and by implication introducing new intellectual property rights so long as these are consistent with the general TRIPS provisions.[59] On this basis, Member states may be able to introduce new intellectual property rights protecting traditional knowledge of their local and traditional communities,[60] including PGRs.

Access to Plant Genetic Resources

Closely related to the issue of protection of TK is the issue of access to PGRs at national level and international collections held at CGIAR (Consultative Group on International Agricultural Research) Centres, on terms that recognize the contribution made by farmers in developing countries in conserving, improving and making available these resources. At present, there are about 50,000 plant samples of more than 3000 crop, forage and agro-forestry species at these international centres. The collection includes farmers' varieties and improved varieties and, in substantial measure, wild species from which those varieties were created and stored in the "geno-plasim" banks of the CGIAR centers. The access to these geno-plasim will now be regulated under the FAO Treaty on PGRFA, through a standard Material Transfer Agreement (MTA). It is the CGIAR's stated policy that such germplasm is held in trust for the world community and should not be subject to IPRs by the Centres or the recipients of the material. Under the PGRFA Treaty access to these genetic resources shall be provided only for research, breeding and training in food and agriculture; for multiple-use crops (food and non-food), their importance in food security will be the determinant factor for their accessibility; the recipient shall not claim any IPR or other right over these genetic resources or their genetic parts and

[57] The EU Biotechnology Directive, in Recital 27 of the Directive provides:
"Whereas if an invention is based on biological material of plant or animal origin or if uses such material, the patent application should, where appropriate, include information on the geographical origin of such material, if known; whereas this is without prejudice to the processing of patent applications or the validity of rights arising from granted patents." This provision thus encourages disclosure but does not carry any legal consequence for non-disclosure. Switzerland in its submission to the TRIPS Council has supported the proposals of disclosure of source of GRs and TK in patent applications and proposes for an amendment of Regulations under the PCT in this regard. If the patent application does not contain the required disclosure, national law may provide for non-processing of such an application when it enters in the national phase. See *Communication from Switzerland*, WTO Doc. IP/C/W/400, 28 May 2003, p. 6. It is in apparent contradiction to the stipulations under the above-mentioned national laws. Such a provision would also be unable to address the concerns of developing countries about misappropriation and may lead to a conflict situation.

[58] Section 41 of the (India's) Plant Varieties Act accepts the rights of communities in developing or contributing significantly to the evolution of a variety and under a procedure would be compensated for their contribution.

[59] Article 1(1) TRIPS.

[60] See Heath and Sabine, *Intellectual Property: Suitable Protection for Protecting Traditional Medicine?* [2003] IPQ 69 at p. 74 where it is noted that just as some countries have opted for additional protection for utility models, so too additional protection for traditional medicine can also be devised.

components in the form received from the Multilateral System.[61] In contrast to CBD's bilateral approach on access to PGRs, the PGRFA Treaty provides a multilateral and regulated framework in this regard.

The CBD in 2002, at COP-VI adopted Guidelines, which the parties may use in drafting their laws and policies "on access and benefit-sharing, and contracts and other arrangements under mutually agreed terms for access and benefit sharing".[62] The Guidelines are voluntary in nature, which the parties may take into account while giving effect to their obligations under the CBD. They provide some background to the discussion on the practical interaction between the IP system and the CBD. The Guidelines suggest that Material Transfer Agreements (MTAs) on GRs may include conditions under which the user in accessed GRs may seek IPRs, and monetary and non-monetary benefits may include "joint ownership of relevant intellectual property rights".[63] Parties have been invited "to encourage the disclosure of the country of origin of genetic resources in applications for intellectual property rights, where the subject matter of the application concerns or makes use of genetic resources in its development, as a possible contribution to tracking compliance with prior informed consent and the mutually agreed terms on which access to those resources was granted." They have further been invited "to encourage the disclosure of the origin of the relevant traditional knowledge, innovations and practices of indigenous and local communities.[64]

As means to implement the CBD requirements for mutually agreed terms, the guiding parameters suggested for contractual agreements, provide that the "provision for the use of intellectual property rights include joint research, obligation to implement rights on inventions obtained and to provide licenses by common consent" and " the possibility of joint ownership of intellectual property rights according to the degree of contribution."[65] In order to seek compliance with the prior informed consent of the contracting party providing such resources and mutually agreed terms, the countries may take measures to encourage the disclosure of the country of origin of the genetic resources and the origin of TK in applications for IPRs.[66] The guidelines to a great extent address the concerns of developing countries without any binding legal obligation.[67] But in contrast to ITPGRFA, which envisages a multilateral system of benefit sharing,[68] the CBD/Bonn Guidelines are premised on bilateral approach, which may not be fair enough when the parties to an agreement would be unequal.

The concerns of local/traditional communities on this matter can be addressed under a *sui generis* regime on plant varieties in an appropriate manner, while according access to genetic resources, as mandated by the CBD. It has been observed that access regimes created by some developing countries have proved to be very restrictive, at the cost of genuine research, which may prove to be detrimental to national interests.[69] The national regime must provide a distinct approach to

[61] See Art. 12 of the Treaty.
[62] See COP-VI Decision VI/24, Access and benefit sharing as related to genetic resources.
[63] See Appendix I and II to the Guidelines.
[64] See Annex to the Guidelines.
[65] Para 43 (c) & (d) of the Guidelines.
[66] Para 16 (d) (ii) of the Guidelines.
[67] Section 21 of the India's Biological Diversity Act incorporates these provisions.
[68] See Articles 13(2) and 19(3)(f).
[69] See Heath and Weidlich, *op. cit.* 61, at 83; Jose Maria A. Ochave, *The Anticommons in Bioprospecting: Regulation of Access to Genetic and Biological Materials in the Philippines,* The World Bulletin, Vol. 15,

facilitate the access to genetic resources for purely commercial purposes and that for scientific purposes for further research and development in this field. The procedure needs to be transparent and less cumbersome for genuine parties. A distinct authority be designated to grant permission to researchers to access and remove biological specimens. The involvement of local/traditional communities must be ensured in decision-making in the matter of access and sharing of benefits arising out of the use of their TK in genetic resources.

Farmers' Rights[70]

Farmers' rights and privileges are not just a matter of checks and balances within the IP system, they are also about recognition and protection for their contributions to traditional knowledge and the need to ensure that they are able to participate equitably in the age of modern biotechnology. Farmers' rights in this context means the right to save and sow seeds of the IP protected varieties/propagating material so long as they are not sold as commercial propagating material or in a manner that undermines the commercial value of the invention to the creator or to be entitled to new varieties and to share in the use of their TK equitably.

The ITPGRFA in Article 9 recognizes the farmers' rights without defining who is a farmer. The Farmers' rights are defined as including: protection of traditional knowledge relevant to plant genetic resources for food and agriculture; the right to participate equitably in sharing the benefits arising from the use of plant genetic resources for food and agriculture; and the right to participate in making decisions at the national level on matters arising from the use of plant genetic resources for food and agriculture. While none of these is necessarily IPR-related, the ITPGR also expressly states that these identified rights do not "limit any rights that farmers have to save, use, exchange and sell farm saved seed or propagating material." The practice, custom and right of farmers in many communities to save seed from previous harvests for use in successive seasons is thus recognised under the Treaty. In most of the discussion on farmers' rights is confined to these traditional rights related to seeds without taking into account the all encompassive rights specified in Article 9 of the Treaty. A *sui generis* PVP legislation must address farmers' rights comprehensively, including the protection of TK, their participation in decision-making related to access and benefit-sharing in PGRs.

While ITPGRFA defines farmers' rights in connection with PGRs in food and agriculture, similar points are likely to arise with animals, as it is also a part of farmers' agricultural activity. The patents on biological inventions may address the issue of farmers' rights on this aspect, with suitable exceptions.[71]

The UPOV Convention, whereas in its 1978 Act allows saving of seeds by farmers from their harvest out of the protected variety, the 1991 Act makes it optional for Contracting Parties to provide these exceptions (Art. 15(2)).[72] Even though, it is not an international obligation to

---

Nos. 1-6, Jan. –Dec. 1999, 150, at 157; C. Fowler, "Sharing Agriculture's Genetic Bounty", *Science* 297 (2002: 157).

[70] "Farmers' Rights' have been defined by FAO in International Understanding on Plant Genetic Resources in 1983,as 'rights arising from the past, present and future contributions of farmers in conserving, improving, and making available plant genetic resources, particularly those in centers of origin or diversity". See FAO Conf. Res. 8/83, 5/89 and 3/91.

[71] For example, even Europe, with its relatively strong protection for biotechnology and patent, recognizes in Article 11 of the European Directive the need to protect farmers' rights.

[72] India's Plant Varieties and Farmers' Rights Act 2001, whilst setting up a system to protect plant varieties, allows farmers to "save, use, sow, re-sow, exchange, share or sell his farm produce including a

provide specific legislative provisions protecting farmers' rights under the Convention, but on the rationales of equity and economics, it is necessary that these rights must be protected legally. Farmers' rights may be seen as a means of providing incentives for farmers to continue to provide services of conservation and maintenance of biodiversity. As noted, the protection of plant varieties contains an inherent tendency to encourage uniformity and reduce biodiversity, to which the traditional practices of farmers are an essential counterweight. Farmers should be supported in recognition of the economic value for their conservation, which is not recognized in the market system, and is to some extent threatened by technical changes and the extension of plant breeders' protection. Thus, the legislative attempts by developing countries must clearly protect the rights of farmers and provide incentives to protect land races.

Public Interest Provisions

Article 30 of the TRIPS allows limited exceptions to the exclusive rights conferred by a patent. Provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonable prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties. Article 8 also provides that members, while formulating or amending national laws, may adopt necessary measures to protect public health and nutrition, and to promote the public interest in sectors vital to their socio-economic and technological development, consistent with the TRIPS Agreement. In this context, developing countries may adopt certain measures consonant to their national needs while enacting a law on plant varieties. Article 7 also has the pious objectives that IPRs should contribute to the promotion of technological innovation and the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge. These provisions together leave enough scope for developing countries to adopt a PVP system consonant with their national interests and help rather than hinder their development.

(a) **Experimentation Defense**

As the patents and PBRs have the tendency to restrict the use of the protected subject matter, except with the permission of the right holder, there is a strong concern over the right to conduct further research and experiments on protected subject matter. Major industrialised countries such as Canada and the United Kingdom have recognised the importance of private non-commercial use defense as well as a defense to cover experimental use on the subject-matter of a patented invention in commercial settings, the same is even more significant for developing countries,

---

seed of a variety protected under this Act in the same manner as he was entitled before the coming into force of this Act." See section 39 of the Act. If India decides to apply for membership of UPOV, the main area of contention is likely to be the issue of farmer' rights. Adcock explains that "the scope of farmers' privilege varies in different national laws, but generally farmers were allowed to continue their tradition of using a part of one year'' harvest as seeds for the next and to exchange seeds with their farm neighbors. These activities were not considered as a part of "commercial marketing" under Article 5(1) of the 1978 UPOV Convention. However, this form of farmers' privilege falls well short of what is allowed under the farmers' rights provisions in [the Indian Act]." See Adcock, *Farmers' Right or Privilege,* [2001/2] 3 BSLR 90 at p. 92. Adcock also notes that UPOV 1991 provides that farmers' rights must recognize the legitimate interests of the breeder and that this usually means payment of compensation (equitable remuneration) for use of farm saved seed. See Article 15(2) UPOV 1991. See also the extensive farmers' rights provisions in the Organization of African Unity's (OAU) Model Law for the Protection of the Rights of Local Communities, Farmers, Breeders and for the Regulation of Access to Biological Resources. Part V sets out farmers' rights that include the right to save, use and exchange and sell farm saved seed/propagating material of farmers' varieties and to use a new breeders variety to develop farmers' varieties, including material obtained from gene banks or plant genetic resources centres. This right does not permit the sale of farm saved seed/propagating material on a commercial scale.

which are obliged to grant IPR protection to biotechnological inventions and plant varieties. They must introduce in their patent and plant variety legislation experimentation defense that goes beyond academic research and covers experimentation of the patented invention in a commercial context.[73] Article 15 of the Act of UPOV Contention, provides that plant breeders' right do not extend to acts done for private non-commercial purposes and for the purposes of experimentation (Art. 15(1)(i) and (ii)).
In the case of biological inventions and plant varieties protection, as they are reproduced naturally, an exception for innocent infringement can be carved out in their laws.[74]

(b) **Compulsory licenses**
In the event when the incentives to breeders by according plant variety rights do not lead to the intended results in the development of agriculture, or in the event that the breeder misuses his right, the mechanism of compulsory licence must be provided by law to ensure the availability and production of seeds/propagating material. This will not only help in meeting the nutritional needs of people but would ensure the food security of the country.

The UPOV Convention (1991 Act, Art. 17) states: 'no Contracting Party may restrict the free exercise of a breeder's right for reasons other than of public interest'. And where a party restricts the breeder's right by compulsory licence to ensure the wide distribution of the protected variety, it will take 'all measures necessary to ensure that the breeder receives equitable remuneration'. This is in line with Article 31 of the TRIPS Agreement. However, Article 31 of the TRIPS Agreement lays down very strict regime for compulsory licenses for patents, which may be tailored according to the national needs in case of plant variety protection.

***Sui Generis* System on PVP for Developing Countries**
The introduction of plant variety protection has significant implications for developing countries since seeds have traditionally been supplied overwhelmingly by farmers themselves and by the public sector, with the private sector playing marginal role until recently in most crops. This scenario will change fundamentally to the detriment of traditional stakeholders unless a proper system is not crafted. From a legal perspective, the protection of plant varieties remains an issue, which is far from settled. This is due to a number of reasons: Firstly, plant variety protection is an issue, which goes beyond giving incentives to the private sector. In fact, while the TRIPS Agreement is the direct trigger for the introduction of plant variety protection, it is not the only relevant treaty. The Biodiversity Convention and the International Treaty on Plant Genetic Resources for Food and Agriculture (PGRFA Treaty) are also of major importance. Secondly, while PVP is directly related to innovation in the field of agriculture, it must also be understood in the broader context, which includes conservation of biological resources. Thirdly, PVP is opposed to the idea that agricultural management should be based on the sharing of knowledge and resources. Rather, it is based on the monopolization of the knowledge. This may be criticised from a conceptual and practical point of view. However, in the context of the widespread ratification of TRIPS and the increasingly tenuous nature of farmers' hold over their resources

[73] See George Wei "Fitting Biological Products within the Intellectual Property Framework: Challenges Facing the Policy Makers", paper presented at Intellectual Property and Biological Resources Conference, December 2003, Singapore) pp. 70. Section 30 of the PVP Act of India provides researcher's rights by allowing "the use of any variety registered under this Act by any person using such variety for conducting experiment or research".

[74] Section 42 of the [India] Plant Varieties Act exempts an innocent infringement from the purview of the Act.

and knowledge, it is necessary to go beyond criticism and understand the additional requirements of the current international legal system with respect to the needs of farmers and more broadly of food security for all individuals. The requirement to protect plant varieties should not undermine the right of Members to protect important public policy goals, including the elimination of rural poverty and the integration of local communities in the development goals.
In according intellectual property protection to plant varieties, developing countries have the following options:

(i) Provide patents
(ii) UPOV based *sui generis* protection (either 1991 or 1978 Act).[75]
(iii) A distinct form of *sui generis* system, conducive to its needs.
(iv) Provide PVP as well as patents, on the line of United States.

As stated above, patent protection is a stronger form of protection. For biotechnology-related inventions it would not be in the interests of the majority of developing countries, which have little or no capability in this technology to grant patents, because of the restrictions patents may place on use of seed/propagating material by farmers and researchers. But taking into account the great potentials of biotechnology in solving their health and nutritional needs, developing countries should utilize the TRIPS flexibility by defining the precise scope of these inventions for patent purposes. They may decide to exclude patenting of life forms, but this step would be controversial, and should instead restrict the scope of protection to microorganisms and microbiological processes. In particular, in the absence of any universally recognized definition of what constitutes a "microorganism", developing countries remain free to adopt a credible definition that limits the range of material covered.[76] It holds true for microbiological and non-biological processes also.

Countries with some credible capability in biotechnology-related industries may choose to provide patent protection in this area. In doing so, they should carve out well- defined exceptions to the exclusive rights conferred by patents, for plant breeding and research, as well as provide farmers' rights on the lines of EU Biotechnology Directive (Articles 11 and 12). The extent to which patent rights extend to the progeny or multiplied product of the patented invention should also be examined and a clear exception provided for farmers to reuse seeds be provided.[77]
In contrast to a patent regime, a *sui generis* system for plant varieties would be most appropriate for developing countries, which will provide them more flexibility to address their concerns. The UPOV (1991) model of *sui generis* system, which is designed on the needs of developed countries, however, may not be able to address the specific concerns of developing countries on the protection of farmer's rights, research exemptions, protection of TK, benefit sharing and regulating the access to PGRs. Rather developing countries should have their homegrown *sui generis* law on PVP, addressing all these concerns in their national interest. [78]

[75] If a country wants to become a member to UPOV Convention now, can do so only by adhering to 1991 Act.
[76] Genes are not microorganisms and neither, under a narrow definition, cell lines, although, for example, the UK Patent Law considers the later to be microorganisms. See UK Patent Office Manual of Patent Practice, Section 1.40. See also, Adcock, M. & Llewelyn, M. "Microorganisms, Definitions and Options under TRIPS", Occasional Paper 2, QUNO, Geneva (2000).
[77] CIPR Report at p. 66.
[78] Out of its 56 members of UPOV, more than half of them are developing countries or countries in economic transition. Others are devising their own *sui generis* model on PVP. For Asian models, see *op. cit.* 1.

Irrespective of the type of *sui generis* system adopted, the countries may exclude non-commercial use of plant varieties and retain the system of seed saving and exchange amongst farmers. They may also require within their domestic laws, the disclosure of sources of any biological material and traditional knowledge that constitute some input in the inventions claimed and proof of benefit sharing with local/indigenous people. Traditional knowledge and inventions of local communities be protected under appropriate regimes and on the understanding that TRIPS only sets out minimum standards and does not prevent Members from adopting other areas of protection. [79]

The State must regulate private sector activities to ensure that they do not impinge on the resources of people who do not have access to sufficient food (which includes ensuring that private sector firms do not intrude on farmers rights) and that their activities sufficiently promote agro-biodiversity. Their anti-competitive practices must be curbed through legislation, and, may be made a part of the *sui generis* legislation. The State must also ensure that there is sufficient R&D in the area of under-utilised crops of high nutritional value. This can be undertaken mainly by public institutions since private seed companies would be motivated by profits. A differential approach between different kinds of crops, viz., cash crops with export potentials and food crops, may be another way to address the issue by providing PVP protection to cash crops only. A variety may be refused protection if it endangers the environment (TRIPS Article 27(2)).[80]

Since the principal custodians of biotechnological know-how are TNCs, which are profit driven; hence their emphasis will be only on a handful of countries with large market potentials. Their research priorities, varieties and marketing strategies will have very uneven and dislocating effects on developing countries' agrarian structures particularly small countries. This situation can be remedied by devising some sort of *quid pro quo* arrangement with multinational companies by giving them access to natural genetic resources in return for developing new varieties for the specific needs of a developing country or on a regional basis, which will be in furtherance of meeting the CBD obligations. The governments in these countries should create a fund by placing a charge on the producers' surplus in proportion to the 'proximity' of the patented or protected life form to a naturally occurring variety on a non-discriminatory basis between the TNCs and local entrepreneurs. The fund can be used to promote environmental causes in the developing world. Moreover, sustainable agriculture requires for its success location-specific varieties, adapted to the local ecological soil and socio-economic conditions, such as irrigation methods. This is also necessary to develop these countries' own R & D capabilities and to set up a core of scientists.

In this regard the participation of farmers who for generations have conserved and improved the crop genetic resources *in situ* can be very crucial. Their participation and co-operation in developing and testing the new varieties is also vital. The *sui generis* system devised by these countries should encourage this nexus between the breeder and the farm families. In order to preserve ecology and biodiversity, countries counteract the excessive use of a single variety by providing adequate incentives for *in situ* conservation of land races or by prescribing a minimum

[79] Articles 1 and 29 of the TRIPS leave enough scope for Members to adopt measures regarding disclosure on TK and benefit-sharing; see also Philippe Cullet & Radhika Kolluru, "Plant Variety Protection and Farmers' Rights: Towards a Broader Understanding", XXIV Delhi Law Review 41 (2002).

[80] The Patents (Amendment) Act (of India) in section 3(b) provides that "an invention the primary or intended use or commercial exploitation of which could be contrary to public order or morality or which causes serious prejudice to human, animal or plant life or health or to the environment" will not be eligible for patent.

percentage of agriculture land to be used for land races in addition to the new varieties. The role of the village folks, including women, who for generations conserved and developed these land races, should be adequately reflected in the legislation, which will ensure not only food security and poverty alleviation but conservation of biodiversity.

Indian Position

In devising a *sui generis* law on PVP, Indian legislation may be taken as one model. India is a party to TRIPS Agreement, CBD and ITPGRFA. In furtherance to give effect to its international obligations under these treaties, it has adopted the Patents (Amendment Act, 2002), the Protection of Plant Variety and Farmers' Rights Act, 2001, and Biological Diversity Act, 2002. Together they address the concerns raised above, including on TK and farmers' rights. Except the Biological Diversity Act, the other two Acts are in force. The Patents (Amendment) Act, 2002, has excluded from patents:

(i) an invention the primary or intended use or commercial exploitation of which could be contrary to public order or morality or which causes serious prejudice to human, animal or plant life or health or to the environment;

(ii) the mere discovery of a scientific principle or the formulation of or discovery of any living thing or non-living substance occurring in nature;

(iii) plants and animals in whole or any part thereof other than micro-organisms but including seeds, varieties and species and essentially biological processes for production or propagation of plants and animals;

(iv) an invention which, in effect, is traditional knowledge or which is an aggregation or duplication of known properties of traditionally known component or components.

The Plant Varieties Act, 2001, though primarily based on UPOV Convention, provides a *sui generis* system for PBRs, which goes beyond the UPOV Convention. For instance, it recognizes the role of farmers as cultivators and conservers, and the contribution of traditional, rural and tribal communities in the country's agro-biodiversity by making provision for benefit - sharing and compensation, and also protecting the traditional rights of the farmers,[81] and has thus acknowledged that farmers' rights can be conceived as intellectual property rights. The Act, in fact, has taken into account the specific socio-economic interests of various stakeholders in the seed sector – from private seed companies to public corporations and research institutions, and resource poor farmers.

The Act recognizes the traditional rights of farmers to save, use, exchange, share or sell their farm produce of a protected variety, which is in line with Article 15(2) of the 1991 Act of the UPOV Convention. However, the farmer is not entitled to sell branded seed.[82] It also acknowledges the rights of farmer to register a new variety, bred or developed by him, and he will be entitled to protection like any other breeder under the Act.[83] The Act also recognizes the rights of the

[81] See sections 39 and 41.

[82] Any seed put in package or any other container and labeled to indicate as protected variety is a branded seed.

[83] Sec. 39. The extent to which this provision will be meaningful in practice is, however, open to debate. To obtain protection, farmers' varieties must conform to the UPOV criteria of distinctness, uniformity and stability. Given that breeding efforts of farmers typically occur *in situ*, and that farmers (unlike breeders in formal breeding programmes) cannot entirely control the agro-ecological conditions in which varieties are bred, it is questionable to what extent varieties claimed by farmers will meet the DUS criteria.

communities and once their contribution is quantified, they will be entitled to compensation from the Gene Fund created under the Act.

The registration of a variety is not allowed in cases where prevention of commercial exploitation of such variety is necessary to protect public order or public morality or human, animal or plant life and health or to avoid serious prejudice to the environment (sec. 29)[84] and prohibits the use of genetic use restriction/terminator technology. The Central Government can exclude any genera or species from the purview of protection in public interest. The Act makes provisions for compulsory license in public interest of protected varieties if the right-holder does not arrange for the production and sale of seeds to ensure that the protected seeds are available to the farmers at a reasonable price (sec. 47). In line with the patent law, the proposed legislation provides that the Plant Varieties and Farmers' Rights Authority shall determine the duration of the license (which may vary from case to case), terms and conditions of the license, viz., royalty and other remuneration to the breeder of the variety; and ensure that the compulsory licensee of such variety possesses the adequate means to provide to the farmers, the seeds or its propagating material at reasonable market price (sections 48-51). The provisions on benefit sharing and compensation, in fact, will be subject to the rules, guidelines and schemes to be framed by the Central Government and the Authority (Rules has since been framed in 2003).

The Biological Diversity Act, which is based on CBD and to some extent on PGRFA Treaty, addresses the issues which are relevant to biodiversity management in general and PGRs management in specific. The main focus of the Act is to regulate access to GRs and associated traditional knowledge by foreign individuals, institutions or companies with the purpose of securing equitable sharing of benefits arising out of the use of these resources with the local people, who are conservers of biological resources and holders of knowledge and information relating to the use of these resources, and to protect knowledge of local communities related to biodiversity. On benefit sharing, the Act takes into account the Bonn Guidelines (section 21). The different provisions of the Act address the problem of bio-piracy.

Together these legislations, however, fail to address the participation of farmers or local communities in decision making or in the protection of TK.

Conclusion

The developing countries, which are mandated to protect biological inventions and provide credible PVP system under TRIPS Agreement, should enact a legislation consonant to their national development goals. For this purpose they should use the TRIPS flexibility. As most of these countries are contracting parties of the CBD, whatever system they chose, that should address the question of validating the Convention on Biological Diversity (CBD) which through disclosure of origin and evidence of prior informed consent and benefit sharing as part of the process of acquiring intellectual property rights over PGR as well as the issue of new *sui generis* rights to protect traditional knowledge (and folklore) nationally and internationally should be made part of it. In fact, their approach should be CBD-centric on PVP protection, keeping in mind the ITPGRFA and Bonn Guidelines.

[84] Compare with Art. 27(2), TRIPS Agreement, and the Patents (Amendment) Act, sec. 3(b).