7. IPR, ECONOMIC DEVELOPMENT AND ETHICS

7.1 Introduction

Economic development in the contemporary world is driven by the science and technology. Advances in relevant technologies and access to them are critical determinants to economic development, leading to poverty alleviation and social security. In corollary, backwardness of nations in S&T capability and their incapability to access and absorb appropriate technologies have become the major force driving the economic divide between the rich and the poor countries. Extreme poverty, low human development and the need for huge investment in human and financial capital over a long period to establish a competent, indigenous S&T capability have trapped these poor countries into a vicious circle with no easy way out from their poverty and under-development of human and social capital. Poverty and under-development are, in addition, causing inefficient and wasteful use of natural resources, leading to rapid resource shrinkage, environment degradation, population increase, poor health and human productivity. Together, these result in stumble development, perpetuate poverty, deprive social and health security and deny an overall dignified life to the people. In this context, the increasing global shift in R&D investment from public science for common good to private science for corporate profit, together with universalization of a rigid intellectual property regime, is virtually foreclosing the chances for developing and least developed countries to access and deploy S&T to mitigate poverty, access healthy life, achieve economic development and offer a dignified life to their peoples.

7.2 IP and Development

Knowledge is the multidimensional outcome of human intellect. It is far more than intellectual property (IP). It is embodied in people, their way of life, their institutions and the materials and technologies they generate. Knowledge is the driver of human progress from all dimensions. The power of knowledge in wealth generation and development has come into sharp focus since the days of industrial revolution and more recently with advances in electronics, informatics and communication technology and biotechnology. According to the classical theory on S&T and IPRs, S&T is the engine of development, and IPRs for technologies is a major fuel ingredient energizing the engine. IPRs are considered to encourage innovation, promote investment in S&T and make the technologies work for public benefit. The history of S&T, from the time of the industrial revolution in Europe, and during twentieth century in the North America and Japan, shows that IPRs contributed to the S&T driven economic growth. However, in the case of developing countries, while indigenous technological capability is a critical determinant to economic growth and poverty reduction, no precise relationship has been established between the IPR system and economic growth.[1] An analysis of

this apparently contradictory paradigm shows that there is a fair and consistent relationship between the strength of IPRs, as existed prior to the implementation of the Agreement on Trade Related aspects of Intellectual Property Rights (TRIPS) and per capita income across countries. More than the IPRs, it is the strength of IPRs which determines the growth of indigenous S&T and the economy in these countries. Indications are that the economic development in developing countries does not essentially require strong IP protection, and most of these countries tend to apply a less stringent IPR regime until their per capita income is, by and large, above the US8000 mark.[2] Anthropometrical factors emphatically contribute to the competitive capability of human intellect. It is well established that manifest and hidden hunger can cause irreversible deficiency in intellectual development. In a world where intellectual development of 174 million under-five children, 90% of them from developing countries, is irreversibly affected by under-nourishment, how will universalization of strong IPRs promote equity in economic development?

The main issue, underlying the use of the IPR system for development, therefore, is to decide what level of IPR system could be effectively used for the technological and economic development of developing countries, and whether such an IPR system can co-exist with the emerging globalization of economy and trade. Responses are deeply divided with strong stakeholder mindsets. Developed countries and business corporations, who may benefit directly from IPR regime, insist on strong IPRs for all countries. Benefits of strong IPR regimes to developing countries, they point out, will include increased investment and consequent technology transfer from outside as well as increased generation of more indigenous innovations. Many developing countries, on the other hand, do not favour strong IPR regimes, particularly in those S&T areas where their indigenous capability for innovations is weak. It is also held that the claimed advantages of strong IPR, whenever realized, are not uniform across all S&T sectors.[3] The present IPR conflict is sharpened by the increasing presence of the private sector in S&T and its rush for establishing exclusive, rigid, legal ownership on the knowledge intensive modern technologies and services in order to leverage such ownership for exclusive trade and other strategic advantages.[4]

There are enough successful cases to establish that countries can cross the economic development threshold without strong IPR regimes. For example, without strong IP protection, as well as with no protection for chemical and pharmaceutical products, some of the East Asian countries, like South Korea, achieved rapid economic growth during the two decades beginning in 1960, which led to their economic transformation from developing to developed. Similarly, Switzerland, Holland and Japan benefited from their ability to technologically catch-up without patent laws for many years after the founding of the Paris Convention. Japan introduced the product patent only in 1976. A weak IP protection in pharmaceuticals provided under the Indian Patent Act, 1970 contributed to rapid and significant growth of India's pharmaceutical industry, particularly in low cost generic medicines and intermediates.[1] Thus, apart from the discussed relationship

between the IPR regime and economic status, there is a discernible relationship between the strength of IPR and the development of indigenous technological capability. In other words, a relaxed IPR regime was one of the chosen routes for graduation to technological capability followed by some developing countries. Some of these flexibilities provided in the IP regimes institutionalized by the Paris Convention stand abrogated with the introduction of TRIPS. TRIPS epitomizes the perverse prescription of 'one-size-fits-all' ideology of social and economic development embedded in the globalization process.

IPR regimes have costs as well as benefits, and this balance tilts differently across countries and groups within countries. The developing countries, being the 'late comers' in the world economy, are inherently disadvantaged, bearing a disproportionate share of costs with respect to the benefits received. From the perspective of developing countries, when most of the innovations originate in developed countries, IPR tends to confer privileges to producers rather than consumers. Only 3% of global patents, according to a recent UNDP survey, are owned by inventors from developing countries, and the rest are filed and held by companies based in North America, European Union or Japan. In the case of biotechnology patents, around 25,000 patents were globally granted during 1990-1995, out of which 37% originated from USA, an equal percentage from Japan, 19% from European Union and only 7% originated from rest of the world, including all developing countries. From the point of developing countries, IPRs are not to be an end in themselves, but a means to promote an indigenous S&T capability as an entry point for socio-economic development, poverty reduction, better healthcare and human development. Hence, the criteria for measuring the social benefits of IPRs are different in developed and developing countries. Therefore, a strong and uniform IPR regime prescribed under the 'one-size-fits-all' principle may essentially hinder development in developing countries. A recent World Bank analysis also suggested that the major beneficiaries of TRIPS in terms of enhanced value of patents are the developed countries, with USA expected to make an annual gain of US$19 billion,[5] while developing countries face an annual loss of US$7.5 billion on royalties and license fees.[6] Therefore, one of the major ethical issues arising from the 'one-size-fits-all' IPR regime is whether it will increase native economic wealth and better living standards for the poor, or lead to a transfer of wealth from poor countries to the rich to further widen the economic divide.

As many of the IP protected technologies are owned by the private sector in developed countries, they are the major beneficiaries of TRIPS mediated strong patent regime. A recent study reveals that if an average developing country were to strengthen its patent index by one unit, local annual average sales of US multinational affiliates would rise by about 2%, which in turn would raise their asset stock by about 16%.[2] There is, however, no clear researched information on how strengthened IPR would impact on economic growth, employment, domestic innovation processes, private sector investment in R&D, access to foreign

technology, and trans-national trade. What is evident from experience is that while strong IP regime alone would not attract outside investment, the weak IPR regime that has existed in some of the East Asian and Latin American countries did not discourage the attraction of substantial foreign direct investments (FDI).[7] Moreover, recent reports from international monetary institutions, such as the Report on Global Development Finance 2002 from the World Bank[8] and the Zedillo Report on Finance for Development[9] do not mention IPR as a factor determining investment. On the contrary, there is overwhelming evidence to suggest that although a strong IP regime may facilitate technology transfer under licensing, it may not promote investment and growth of indigenous S&T. It could rather choke the domestic R&D in developing countries. The deficiency in human and technical capacity to innovate competitive technology also makes strong IPR irrelevant in stimulating R&D in many developing countries. Apart from the lack of technological capability, some countries also lack economic strength to avail the social benefits of patents. The UK Commission on Intellectual Property Rights, after an extensive study of the IPR system in developed and developing countries, concluded that an IPR system suitable to the developed countries most often causes far higher costs than benefits when applied to developing countries, and IPR does not help in poverty alleviation.[10]

7.3 IPR and Public Health

Improvement of public health is one of the most effective means to reduce poverty in developing countries; poor public health is inextricably enmeshed with poverty. Fundamental to the improvement of public health is access to medical care and safe, affordable and effective drugs and vaccines. A strong patent regime provisioned under TRIPS, is expected to make drugs inaccessible to poor people in two ways. First, strong patents may lead to strong monopolies, which, in turn, may encourage high prices and consequent unaffordability of patented drugs by the poor. Second, by preventing local manufacture or parallel importation of cheaper generic drugs, governments are incapacitated from arranging alternate affordable supplies. These negative impacts are widely recognized for their serious implications to the public health and development needs of many poor developing and least developed countries.[11] It was the private sector pharmaceutical industry from the developed countries, which lobbied for the global extension of IP rights on the plea that such strong global IP rights are essential for more investment in drug research and development of new drugs.[12] How much such a strong patent regime would be helpful to developing countries in gaining access to existing drugs, and for developing new drugs for better healthcare, is disputable.

Apart from some health problems which are common between developed and developing countries, several major health problems, such as malaria, TB, yellow fever, sleeping sickness, etc., are exclusive to developing countries. As these diseases are not important from the point of developed countries, the pharma industry based in these countries does not give priority to drug development against

these diseases. Globally, about 95% of the investment in pharma R&D is located in developed countries. This investment is also highly skewed sectorally. The profile of R&D investment reveals that the private sector contribution in 2000 was US$44 billion,[13] while the public sector investment in 1999 was US$37 billion.[14] Less than 5% of these investments were deployed on R&D concerning diseases exclusive to developing countries.[15] Hence, the majority of the drugs are essentially developed for the health problems of developed countries and made available to developing countries for the same health problems as technological spill off. Out of the estimated 1393 drugs approved between 1975 and 1999, only 13 were specifically developed for diseases exclusive to developing countries.[16] However, when it comes to market share, 20% of the global drug market, US$406 billion (estimated in 2002), is contributed by the developing countries.[17] According to the Global Alliance for TB Drug Development, although the size of the world market for new and improved TB drugs promises a fair financial return under IP protection, the private sector does not opt to invest in R&D for the development of these drugs, in the absence of major investment support from the public sector.[18] The private sector undervalues vaccine-based preventive healthcare, because it is a high risk/low return investment area, despite its significant social return in the healthcare strategy of developing countries.[19] This takes one to the logical conclusion that a strong global IP protection is beneficial largely to the pharmaceutical industry for increasing its market size and profit rather than stimulating it to expand its R&D to develop new drugs primarily targeted to the health problems of the larger number of people in developing countries.

Wherever medicines are available, affordability is important for access. Therefore, it becomes important to understand how a strong IPR influences the affordability of medicines. Access to medicines, in poor countries, is largely determined by their prices, although other infrastructure aspects are also important. There is a large body of evidence from developed countries that prices of patented drugs are quite high and that prices fall steeply as soon as the patent is expired and generic producers enter the market. Introduction of a strong patent regime in developing countries is predicted to raise the drug prices, to the tune from 12 to 200%, or more.[20, 21]

In this context, the exploitation of subtleties in the IP rules by pharma companies to 'evergreen' their patents beyond the 20-year life of original patents only aggravates the accessibility to drugs by the poor. The commonly deployed 'ever greening' methods are seeking new patents on an old drug by changing the drug delivery methods, by reducing dosage regimens, by formulating new versions or combinations of its active ingredients and on its metabolized products. All these, in effect, delay production of cheap generic substitutes of the old drug, whose initial patent has already expired. As a business strategy, it appears, evergreening has no limits. Many of the new molecules entering the market are the 'me-too-drugs' clan, so called for their similarity to existing drugs in terms of chemical structure and therapeutic effects. Driven by the increasing cost of developing and testing

entirely new compounds, there is a pressure within the industry to consolidate and stretch their profits by holding onto the rights of highly profitable drugs. Some of them, even after lapse of patent, deploy their effective trademark and market promotion skills to gain market advantage over generic producers.

The second alternative for price reduction is differential pricing under market segmentation, drug donation, allowing parallel imports and compulsory licensing at the discretion of the State. These are being strongly resisted by the pharma industry for their impact on profits. However, there are a few instances of either genuine or forced generosity by the pharma industry of granting differential pricing, donating drugs and allowing parallel importation. For example, Merck has offered to sell anti-AIDS drugs in developing countries at no-profit prices.[22] Similarly, Boehringer Ingelheim has offered to donate one of its drugs free of charge for five years to a developing country mother-to-child AIDS transmission prevention programme. The case of South African AIDS treatment programme illustrates the huge differences between the patented and generic triple therapy drugs and how parallel importation under such circumstances may help governments in tackling a serious healthcare crisis.[23, 24] The retreat made by the South African association of multinational pharmaceutical corporations from the patent infringement proceedings initiated against the parallel importation by the national government in the face of adverse publicity, is notable in this context.

Even without patents, it is difficult for many poor people to access the necessary drugs. About 80% of the people in developing countries are unable to buy pharmaceuticals at all. Even in India, where the prices of many drugs are comparatively much cheaper thanks to the absence of no product patent for pharmaceuticals and to the development of a large generic drug industry, the proportion of people who can afford to pay for drugs is only around 30%. Many people in developing countries continue to depend mainly or exclusively on traditional remedies such as herbal formulations.

The strong patent rules being enforced through TRIPS upon developing countries bring up many ethical issues. The first ethical issue involves the consequences of inaccessibility of pharmaceuticals arising from monopoly-driven high prices and the unwillingness of multinational pharmaceutical corporations to allow differential pricing, patent donation, compulsory licensing or parallel importation. The high prices may compel poor sick people either to spend more on medicines, and consequently less on other essentials of life such as food, shelter and clothing, or to forego medicines and face long suffering from illness with premature death. It is a human rights issue transcending the economic aspects of accessibility.

The second ethical issue arises from the broadened patents on process and product, evergreening patents under the legal subtleties of patent rules, and large scale patenting of DNA sequences and gene-based diagnostic technologies. Liberal patents on products and processes with broadly claimed subject matter virtually

exclude a broad area for further innovation, and facilitates augmenting the monopoly of the patent holder on the area on permanent basis, more or less. This may also exclude a large sector of pharmaceutical R&D outside the reach of a late-entering developing country's R&D. The 'gold rush' on gene patenting, following the publication of the human genome sequence, has largely succeeded in relaxing the norms of patent in many countries. The established gene patenting norms, such as isolation, cloning, and deciphering the nucleotide sequence and function, had been grossly ignored to grant patent to thousands of computer-identified genes with speculative function and uses.[25] Patents on gene sequences that could be used to diagnose diseases have far reaching ethical implications. For example, the patents held by the US company, Myriad Genetics, on the BRCA1 gene, which is linked to susceptibility to breast cancer, virtually stops others from developing alternative diagnostic tests.[26] It has been argued that patenting of gene fragments used in basic research is a "tragedy of anti-commons," suggesting that such patents place undesirable restrictions on the ability of other scientists to use such gene fragments in their own research.[27]

The third ethical issue is the legal hurdles being erected before developing countries on their rights to determine the grounds on which compulsory licensing is granted and the right to determine what constitutes a "national emergency or other circumstances of extreme urgency." These are important exceptions that seek to make necessary drugs affordable during times of epidemics, mass suffering and death. Although the Doha Ministerial Declaration committed "the right of each Member to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted and to determine what constitutes a national emergency or other circumstances of extreme urgency,"[11] the multinational pharmaceutical lobby is on an all out effort at the ongoing negotiations in the TRIPS Council to deprive these rights to Members. [Negotiation on paragraph 6 of Doha Declaration[11] on the TRIPS Agreement and Public Health at TRIPS Council reached on an agreement in 2003 to allow countries without pharmaceutical manufacturing capacity to import generic versions of drugs still under patent during situations of national emergency or other circumstances of extreme urgency].

The fourth ethical issue associated with drug development and clinical evaluations is the blatant use of poor people in developing countries without proper "informed consent" or "genuine consent." Several unethical instances have come to light where drug evaluators, both public and private, have contracted poor subjects from developing countries for clinical evaluations for which subjects on informed consent are not available in developed countries, or the clinical trial on the specific test molecule is not permissible in accordance with bioethics guidelines of these countries. A more recent clinical evaluation, which stirred up the concern of medical profession and bioethical bodies, pertains to the evaluation of zidovudine, an anti-HIV drug for pregnant mothers, conducted by US researchers on African pregnant mothers.[28] Questioning the unacceptable ethical standards used by the researchers for this evaluation, the *New England Journal of Medicine* and *The*

Lancet charged them with using double standards by adopting test methods unacceptable in their home country. This revelation prompted the US National Bioethics Advisory Committee and the Nuffield Council of Bioethics to come out with a new set of guidelines and recommendations on the conduct of clinical evaluations.

7.4 IP and Agriculture

Food is essential for the survival of human beings. Hunger is a manifestation of the denial of the universal right to food. Without access to food in right quantity and quality there can be no good health and well-being of people, thus, disallowing the promotion of their human dignity and self-respect. Hence, productive and sustainable agriculture is as important as good health for economic growth and social security in developing countries. Agriculture is the backbone of the economy in these countries, providing food and livelihood to a vast majority of people in some countries. For instance, the agriculture in many small island countries in the Pacific is specialized in very few non-food plantation or commercial crops, whereas their food security and economic growth depends on international trade and its terms. Nearly three-quarters of the world's poor live and work in rural areas, where agriculture directly determines their food and livelihood security, apart from its all encompassing influence on overall economic growth. It is these poor farmers in developing countries who are ensuring their food security. Plagued with low resource capability and productivity, a mere rise in agricultural productivity may profoundly impact increased incomes, employment, trade and agro-processing, access of the poor to food and decreased poverty. For instance, it is estimated that a one percent increase in production could reduce the poverty of 6 million people in Africa by raising their income above one USD per day.[29]

Most commonly practiced agriculture in many poor developing countries uses land races and traditional farming methods. It is this agriculture, practiced by the poor farmers of developing countries, which had been responsible for the creation and conservation of most of the crop diversity, which is fundamental to today's global food and agriculture resources. Ninety percent of global biodiversity is concentrated in less than 10% land area around the equator; 70% of this is endemic to 12 mega-biodiversity regions.[30] These are the very regions that are the primary or secondary centres of genetic diversity of more than 80% of the crops used in agriculture and where the world's poorest live. This biodiversity and associated knowledge of their various characteristics, adaptive features, etc., set the entry point for the scientific improvement of crops. Way back when man started agriculture, the bio-diversity supporting agriculture was freely available across farmers, communities, researchers and countries with no restrictions and ownership rights. Cardinal to this is the total freedom that farmers have to save, sow, exchange, or sell seeds or other propagating material of all plants. These rights of farmers in regard to seeds is fundamental to the large genetic diversity created and conserved by them all over the world, particularly from the developing countries

of Asia-Pacific, Africa and Latin America, where lie much of the genetic diversity of crop plants.

Historically, IPRs were applicable only to industrial inventions and not to plants and animals and other living things, although the improvement of plant and animal stocks and discovery of new living entities economically useful to humans were essential aspects of the agricultural process. These processes and products were kept outside the purview of IP protection in all countries until 1930, when the tradition was first broken by the USA when it conferred patents to vegetatively propagated plants. Thirty years later, in 1961, with the entry of the private sector in European plant breeding, the plant breeder's right (PBR) was introduced through the International Union for the Protection of New Varieties of Plants (UPOV).[31] One of the earliest microbial patents was granted to Louis Pasteur in 1873 in the USA for yeast. A system of deposition of patented organisms was initiated in 1980 with the establishment of Budapest Treaty on Microorganisms.[32]

The floodgate of patents on genetically modified organisms, genes, nucleotide sequences and genomes was opened in USA with the controversial split judgment of US Supreme Court in 1980 in Anand Chakrabarty vs Diamond. Coming to the PBR, it confers exclusive rights to the breeder of a plant variety to produce, store and market its propagating material. PBR differs from patent right to the extent that it accommodates the traditional rights of farmers (UPOV terms as *'farmers privilege'*) to save, re-sow, exchange and sell seeds of protected varieties, and the researcher's right (UPOV terms as *'researchers privilege'*) to freely use the protected variety for research, including evolving new commercial varieties. PBR also allows adequate legal space to the State for compulsory licensing in the public interest. UPOV, over the years, with the revisions of the Convention in 1978 and 1991, has strengthened the PBR by narrowing the scope of the farmers' and researchers' privileges and minimizing the operational space of compulsory licensing.

7.5 IP and Ethical Issues

There are many important ethical issues involved in the patenting of life forms, including plants and animals, microorganisms, cell lines and gene or DNA sequences. Eligibility of an invention under conventional patent protection demands novelty, involvement of an inventive step (non-obviousness) and utility of the invention. The conventional distinctions made between invention and discovery were overlooked for extending patent to biological systems, beginning in 1980 with the advent of the Budapest Treaty on Microorganisms and advances in Biotechnology. From the classical interpretation of inventions, life forms and their components are not patentable subjects. However, those supporting patenting of life forms argue that considerable ingenuity is involved in locating, isolating and describing molecular biological matter, which was until then unknown to the world, and these forms have industrial utility. Opposition to patenting of life forms

argues that all life forms, including the patented, are reproduced by essentially biological processes and the human intervention is limited to either identifying/ developing a new plant variety from/by using pre-existing varieties, isolating and characterizing a microorganism from a habitat, dressing a natural DNA sequence without 'junk DNA' and finding its natural function, or expressing such genes in another genome. These, no doubt, are skilled procedures, but they are not inventions qualifying for patents. The most unethical aspect of patenting whole biotechnologically bred organism *in lieu* of changes made in one or few genes is that many thousands of unmodified native genes present in the genome of the patented organism are excluded from the reach of other researchers, although the patent holder has no innovation claim on these genes. Even in recombinant DNA technology, the genes involved are not invented, but recombined in a manner that does not happen in nature. Therefore, ethical practices in science demands that genetic resources used in agriculture must be excluded from IPR regime.

The primary basis of granting a patent to a DNA sequence or gene relies on establishing expressed sequence tagging with function and industrial applicability. In fact, the basis of establishing single function for a gene, such as coding for a particular protein or that it is associated with a particular disease, is problematic. It is simplistic to assume that each gene has independent function, that all gene expressions involve protein-making processes, and that the linear sequence of each gene is discrete without overlap. Although the DNA molecule is not well understood in all its complexities, what is hitherto revealed suggests that no gene functions in isolation, not all genes are involved in the protein making process and there are sequence overlaps in the linear arrangement of genes. Therefore, treating genes as patentable inventions on said criteria is more a reflection of ignorance than of insight, and represents greed for appropriation of a public entity. The rush for privatizing genes through patents is ever increasing following the publication of the human genome sequence in 2001. Genomics has now become a professional process, which can be mechanically performed with trained manpower, equipment and large resources enabling private and public institutions commanding such resources to analyze the genome of any species and to patent their genes. The rate of this patenting has increased during the last decade, from 6,000 sequences in 1990 to over 355,000. There is an aggressive patenting spree by biotechnology firms in developed countries largely to exclude others from as many genes as possible in an effort to create a business monopoly to control future research. Several of these patents have started stifling upstream research in many areas. Obvious consequences are the exclusion of several R&D areas for the non-patent holders, and an enormous increase in the cost and time for R&D on negotiations and payments of royalty or licensing fees. Developing countries will be the sure victims of these unethical practices, adding further cost and hurdles to their developmental efforts.

The multiple patenting in agricultural biotechnology is already causing problems for research advancement. This may be well illustrated with 'golden rice', which

was genetically engineered to synthesize beta-carotene in endosperm with a view to address the Vitamin A deficiency in the diet of millions of poor people. The technology, involving three genes, is protected by as many as 16 important patents and 72 potential product and process IP barriers owned by 32 companies and institutions.[33] Getting around all these patentees to negotiate and to agree to cooperate for grounding further research for the commercial development of golden rice is very complex and time consuming, apart from the high possible cost required for licensing out the rights of most of the patent holders. Also, in the absence of a clear view on the commercial feasibility and prospect of golden rice, it is not easy to negotiate any possible high license fee claims from some of the patentees. This illustrates how biotechnology innovations promoted by patents may abort further development opportunities, particularly in developing countries. It is in this context that the large multinational corporations resort to buy outs and mergers to consolidate business on the strategic patents. For example, now five biotechnology giants from North America, Europe and Japan own 70% of the 25,000 biotechnological patents granted during 1990-95. Such concentration of high-value IPR protected technologies in the hands of a small number of global conglomerates may, in fact, aggravate the disadvantages by eliminating competition.

From the point of developing countries, the choice of granting either patent or the PBR on a plant variety has profound importance. Of first importance, is how far such a choice may impact the current and future food security of country, and to what extent it may promote crop improvement research. All new plant varieties, expected to be superior to the old in yield or quality or some other respect, are created from pre-existed varieties, which are part of the genetic resources. Therefore, capability to develop a new plant variety shall be restrained by free access to appropriate crop genetic resources, including the extant varieties in commerce. When some of these genetic resources are excluded from access by IP rights, the set back to crop productivity-dependent food security could become serious in many crops. The legal provisions governing access by no means remedies the disadvantage of a poor country. The second important issue arises from the impact of PVP on the livelihood of poor farmers who eke out a meager living either exclusively or largely from agriculture. An important and immediate impact of PVP may be on seeds, with high cost and consequent inaccessibility to poor farmers, and on restrictions of the traditional right of farmers to save, use, exchange and sell seed. The impact of this will be stronger on poor farmers. A major study on the impact of PVP in developing countries shows that PVP largely benefited the seed industry, and to some extent the commercial farmers, while it neither led to increased availability of planting material to farmers nor benefited the poor farmers in raising their income.[34] On the contrary, the PVP severely restricted the traditional rights of farmers on seed, which had more adverse impact on poor farmers. Another example is that establishment of PVP in Kenya facilitated the introduction of many varieties of flowers and vegetables by the foreign-owned commercial exporters. These introductions, however, were neither relevant to the

poor Kenyan farmers and the crops they largely grow nor did they stimulate local research for developing better varieties of flowers and vegetables.

The third important issue is associated with the morality of granting ownership on living entities through IPRs. As discussed earlier, IPRs were evolved to promote industrial technological innovations possessing public utility. Although improvement of plant and animal stocks and identification of new, economically useful living entities were essential agricultural processes, the IP on such living systems was held antithetical to different religio-ethical value systems. It was this consensus on underlying value systems that held the biological resources as *the common heritage of mankind*. Moreover, plant genetic resources, which are essential for developing new varieties, have been conserved and improved continuously by generations of poor farmers from many developing countries. But for their past and present contributions on intelligent selection and diligent conservation, neither the large genetic resources available in each crop nor the knowledge associated thereto would have been available to modern scientific plant breeding. In recognition of this critical role being played by farmers, and to promote this role in the larger interest of future global agriculture, in 1983, the FAO International Undertaking on Plant Genetic Resources (IUPGR) developed the concept of "Farmers' Rights," and defined it as the "rights arising from the past, present and future contributions of farmers in conserving, improving, and making available plant genetic resources, particularly those in the centres of origin/ diversity."[35] Patent or PBR excluding Farmers' Rights is ethically unacceptable and a threat to the community-based generation and conservation of genetic diversity supporting agriculture and future food security of nations. This threat unfortunately has increased with the adoption of TRIPS, wherein "protection of plant varieties by either patent, or an effective *sui generis* system or a combination thereof" is mandated.[36] Denial of Farmers' Rights constitute a direct violation of Article 1 of the UN Covenant on Economic, Social and Cultural Rights, which stipulates that "in no case may a people be deprived of its own means of subsistence." At the WTO, the African Group of countries, the 'like-minded group' of countries and the developing countries, in general, have shown clear opposition to the concept of IPRs over life.

Another ethical dimension introduced by the IP protection on living entities mandated by TRIPS is its inconsistency with the Convention on Biological Diversity (CBD) and the recognition of the right of local communities to biological resources (BRs) and associated traditional knowledge (TK). This inconsistency is promoting piracy of BRs and TK from many developing countries. TRIPS is unifocal in ensuring the IPR on 'innovations' based on BRs or associated TK, with an apparent assumption that the related prior art, as material or knowledge, is freely accessible with no legal encumbrances. Such an assumption ignores the legally binding major provisions of CBD on national sovereignty over BRs and TK *inter alia* the responsibility of State on the facilitated access to them with prior informed consent, and on the requirement of parties accessing them, establishing IPR on them

and making commercial exploitation of components of BRs and TK for the sharing of benefit with local communities.[37] Few of the known cases of biopiracy and intrusive patents on the BRs and TK belonging to communities of developing countries are those concerning turmeric,[38] neem,[39] ayahuasca,[40] hoodia,[41] and, smokebush.[42] Thanks to the Doha Ministerial Declaration this inconsistency between TRIPS and CBD is to receive attention at the ongoing negotiations in the TRIPS Council.[43] A proposal at TRIPS negotiations by developing countries led by India wants patent applications to declare sources of BRs or TK used as the prior art, and to produce evidence on prior informed consent and benefit sharing, wherever required.

The fourth important ethical issue arises from the often made claim that IP protection of plant varieties stimulates higher private investment in crop improvement research, which benefits all farmers, including the poor in developing countries. The benefits possible from increased R&D are on two counts: 1) from the availability of better and better varieties and consequent economic gains accessible to farmers through their cultivation, and 2) from the benefit share eligible to concerned communities with the commercialization of products or processes developed from the BRs and TK conserved by them. The first benefit pre-supposes that plant variety protection (PVP) leads to increased variety development and continuous accessibility of farmers to superior varieties. Hybrid variety breeding attracted considerable private investment, even without the PVP, because the hybrid technology by itself has a strong built-in protection. For this very reason, there is a high private sector presence in the hybrid seed sector of many developing countries, even where there is no PVP. Hence, investment on hybrid variety research by private sector cannot be attributed to the PVP. Setting the hybrid seed sector aside, a US study has shown that the introduction of PVP does not increase the total R&D activity, although the number of protected non-hybrid plant varieties significantly increased in certain crops, with increased seed sale by the private companies.[44] Rather than increase in R&D investment and direct benefit to the farmers through increased yield or economic return from new varieties, the PVP appears to have enlarged the seed market of private companies through market promotional and merger processes. Another study on the impact of PVP on wheat breeding and yield in the USA also shows that PVP neither contributes to increased private investment nor to increased yields, while the share of acreage sown under private varieties significantly increased.[45] Thus, the principal object of PVP to promote private investment in non-hybrid variety research remains largely not served even in developed countries[46] where PVP was introduced with stringency much earlier. With respect to the benefit sharing to eligible farming communities, there is no instance hitherto on sharing the commercial benefits accrued from PVP with the eligible community. In fact, this CBD principle is yet to gain acceptance for implementation in developed countries and by their private sectors.

Hence, a checklist of considerations for developing countries, while complying with TRIPS on PVP legislation, shall include whether the kind of PVP allowed would benefit the agricultural development through increased private investment in crop improvement, strengthen food security, promote livelihoods of people depending on agriculture through employment and other agri-business-based income generation, encourage conservation of biodiversity by local communities, or promote agricultural foreign trade. On the global agricultural R&D scenario, the public sector investment from developing countries, by a 1995 estimate, is US$11.5 billion.[47] which is about one-third of the global agricultural R&D investment. Out of the remaining, the R&D contribution from the Consultative Group on International Agricultural Research (CGIAR) is around US$0.34 billion, from the public sector of developed countries, US$10.2 billion, and from the private sector, US$11.5 billion.[47] Only 6% of this private sector R&D investment is directed to agriculture in developing countries. What is notable is that while the private sector has a relatively forceful presence in health and agricultural R&D of developed countries, its investment in these two sectors in developing countries is very low and the public sector in some of developing countries has a better foothold in their agricultural R&D. In the context of increasing entry of the private sector in the agricultural R&D of developing countries, it is important to note that the public interest of R&D is better served by promoting competitiveness and ethical mainstreaming in technology ownership and transfer.

7.6 IPRs, Human rights, and Development

IPRs are usually seen from economic and legal perspectives as the ownership rights for the exclusive use of inventions and creative works. Apart from these perspectives, there is a human rights dimension to IPRs as recognized in the Universal Declaration of Human Rights (UDHR). The principle cutting across IPRs and basic human rights became legally binding when the International Covenant on Economic, Social and Cultural Rights came into force in 1976. Article 15.1 of this Covenant affirms that the general public has a legitimate interest in intellectual productions and a right to benefit from them, and that IPRs should contribute to the scientific, cultural and economic enrichment of society. The right of society for social benefit from IPRs, and the requirements of IPRs to enrich society for its scientific, cultural and economic advancement, needs to be understood and applied in tandem with other Declarations and Covenants of the United Nations. Poverty, pestilence and under-development rampant in developing countries attract Article 25 of UDHR on the right to food, the right to adequate medical care, health and well-being and the right to development to access an adequate standard of living. The Millennium Declaration of the UN General Assembly sets poverty reduction as the major global agenda for all nations, with the target on people earning less than US$1 per day per person (based on purchasing power parity). The persistence of extreme poverty among 1.2 billion people, the majority of them in South and Southeast Asia, is also a challenge to the rights provided under

Article 22 of UHRD on social security and economic rights, and social and cultural rights indispensable for the dignity and free development of personality. The irreversible impact of poverty on low birth weight of children, their intellectual and cognitive under-development due to pre- and post-natal malnourishment, and the lack of opportunity and access to healthcare and education, most common in developing countries, constitute the first exclusive principle against equity in a global economic order styled with a strong and universal IPR system. The UN Sub-Commission for Protection and Promotion of Human Rights captured this conflict when it declared that "*there are apparent conflicts between the IPR regime embodied in the TRIPS Agreement, on the one hand, and international human rights law, on the other, and the former violates the right of everyone to enjoy the benefits of scientific progress, its applications, the right to health and the right to food."* Ethics, rather than economic gains, takes centre stage in the resolution of such conflicts. Such resolution has also to be an affirmation of the Declaration on Right to Development (DRTD) adopted by the UN General Assembly in 1986, which declared the right to development is "*a universal and inalienable right that every human person and all peoples are entitled to, in participating, contributing and enjoying economic, social, cultural and political development by which all human rights and fundamental freedoms can be realized*."

The collective will of the world and the rights to human and economic development, the right of access to food, medical care, health and well-being, and the right to social security shall stand denied or limited in a global IPR regime being styled under TRIPS. It will not only pose a serious hurdle to development in all core economic sectors, like science and technology, indigenous healthcare systems, agricultural production, food security, livelihood of rural people depending on agriculture, and indigenous industries in developing countries, but also exacerbate the existing deep rich-poor divide. For many poor countries, a strong IPR regime will not help in reducing poverty, increasing accessibility to medicines, increasing employment and income, or accessing the economic, social and cultural benefits of patented technologies. Hence, it is important that while accepting the legitimate role of IPRs in each socio-economic paradigm, over exertion of IPRs in developing countries to restrict their ability to attain scientific progress, their economic, social, cultural and political development, and their rights to health and rights to food have to be forcefully rejected. These rights are entitlements of the poor and are not extended as mere charity from the rich. All countries in the world have moral and ethical responsibility to facilitate access of poor countries to these rights; such access should not be delayed or denied. The sovereign rights of the States to harmonize their national legislations and policies on IPR in accordance with international human rights obligations and principles in a manner to promote indigenous science and technology processes, achieve access to public health for all, promote the advancement of agriculture without displacing the livelihoods of dependent people, sustain traditional life styles and cultures, and advance overall economic development as exhorted by different Resolutions of the UN, have to be asserted.

In the context of the integration of globalized economic and international trade, there is an increasing divide between the UN system, on the one hand, and intergovernmental institutions outside the UN system, like the Bretton Woods institutions and WTO, on the other, in upholding ethics and equity. These institutions are clouted to effectively bypass the UN system on global regulation of economy and trade, largely on economic strength, diplomatic muscle and political maneuverability, where rights, ethics and equity are often compromised. The Bretton Woods institutions with their principal policies on liberalization, deregulation and privatization, oppose the Right to Food in their practices. Jean Ziegler, the UN Special Rapporteur on the Right to Food, states that, "we must search for other means of integrating human rights and Right to Food into the rules of international trade." The insensitivity of these organizations in a world where an average of 10,000 people, 33% of them being children, are allowed to die every day due to lack of food is a challenge to the integration of morality and ethics in the globalization process.

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