Biotechnology and IPR Regime: In the Context of India and Developing Countries

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The word 'biotechnology' was actually coined early in the 20th century by an agricultural engineer from Hungary, named Karl Ereky, who explained it in such a way that the technology which include all such work by which products are produced from raw materials with the aid of living organisms. Subsequently, over the period, the definition of biotechnology acquired a confusing status due to various interpretations. The first official broad definition given by the US Office of Technology Assessment which states that "biotechnology, broadly defined, includes any technique that uses living organisms (or parts of organisms) to make or modify products, to improve plants or animals, or to develop micro-organisms for specific uses" is also considered now void. In the broadest sense, the term "biotechnology" encompasses techniques applied to living organisms and parts thereof to produce, identify or design substances or to modify organisms for specific applications. Thus there may be many definitions of biotechnology as it is highly multidisciplinary involving almost all areas of science or to say, biotechnology combines disciplines like genetics, molecular biology, biochemistry, embryology and cell biology, which are in turn linked to practical disciplines like chemical engineering, information technology, and robotics.[1]

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Biotechnology can be traced back to various stages of its development. The first generation biotechnology can be based on the traditional knowledge in various tribes like preparing fermented foods, medicinal distillates, etc. Second generation of biotechnology may be considered when the utilisation of micro-organisms started on industrial scale during the Pasteur era which involved mass production of alcohol, fermentation of antibiotics, development of classical vaccines like for cholera, typhoid, yellow fever, etc. This generation can be considered as the longest one as the mass production of vitamins, amino acids, organic acids as well as plant tissue culture and animal breeding methods were also developed. The third generation of biotechnology can be called as "modern biotechnology" when the rDNA techniques, hybridoma technology, polymerase chain reaction (PCR) and cloning methods emerged during post-Second World War advances in molecular biology. The fourth generation of biotechnology would see further advances where interdisciplinary techniques like information technology and nano-technology would get involved in further advancement of this discipline, especially utilising the bioinformatics, which is the foundation of modern biotechnology. Rapid advances in information technology, particularly in the area of bioinformatics, have played a critical role in breakthrough applications of modern biotechnology in medicine and agriculture. Bioinformatics, broadly defined as the use of computers to handle biological information, has made possible the "genomic era". Bioinformatics provides the computer tools and databases to search, store, analyze and compare these data and to use them to develop, among others, safer and more effective medicines as well as higher yielding, more stress-resistant crops that have the potential for accelerating human development. However, as the *Human Development Report 2001* points out, this potential cannot be realized unless two conditions are met: First, that the modern biotechnology has to be utilized to address the key health and agriculture challenges facing poor countries. Second, modern biotechnology has to be utilized through a systematic approach that allows potential risks to human health, environment and social equity to be effectively assessed and managed.

The modern biotechnology, which is a late 20th century phenomenon, is the result of scientific advances that go well over a century. With the advent of modern biotechnology, the innovation in commercial biotechnology has been taking place the world over. However, the USA has pioneered the commercial biotechnology and

can be called as the world leader due to various reasons. The other successful commercial biotech countries are Japan and Europe especially UK, Germany and France where the industries have enjoyed the benefit of ground breaking research carried out in universities and other public funded research institutions. Biotechnology and genomics have created enormous commercial opportunities in the area of healthcare, agriculture, environment and industrial products.

In the past one and half decade, India has shown excellence in scientific performance as evidenced by number and quality of publications made each year in international journals with the research leads on cover pages and various citations of Indian authors, but its technological and commercial performance is low as indexed by the number of patents issued per unit of investment made in R&D. There is considerable debate going on the IPR issues since India acceded to PCT, but still there is lot to be done in the awareness generation on the IPR issues. In the light of India's adoption of the recent Patent Amendment Bill of 2005, the product patent would be enforced. Further, the on-going and preparative negotiations under GATS, especially for the R&D service sectors in general and biotechnology R&D, in particular would have a major impact on the biotech business of India and the other developing countries.

Biotechnology R&D and IPR Issues

The ownership and exploitation of intellectual property rights are the key factors in determining the success of any technological innovation introduced in the market that provide the means for technological progress to continue, to be made and thereby support the competitiveness of industry of the country. IPRs make it possible to develop strategies for dissemination and transfer of technologies in such a way, which may provide maximum societal benefits. It is a well-known fact that a country's economic and social success is utmost when different members of society have a common understanding, clear division of labour and responsibility with a common understanding for the shared societal values. The efficient management of IPRs is thus crucial in providing the right incentives for continuing technological innovations. The IPRs are thus helpful for new business opportunities and for value adding knowledge-based industry. It is high time that India rapidly adapts to the challenges posed by a continuously evolving technological environment of the world.

The regulatory mechanisms in IPRs have their own problems in the coming scenario of emerging technologies especially in biotechnology. The regulatory reform-initiatives are further required to streamline and sort out the problems in the new frontiers of IPR system. This would give further competitiveness in other significant economic sectors involving copyright, geographical indications, right to information to the society, patenting, etc. The patenting of new technologies, in the presently highly competitive environment provides the most robust system in the IP protection. Nonetheless, the biggest problem, which can be mentioned, is the copying of technologies that is becoming more and more frequent with the emergence of new technologies. For example, 60 per cent of all patented innovations are imitated on an average within four years; the ratio of imitation time to innovation is on an average of 70 per cent; the ratio of imitation cost to innovation cost is on an average of about 60 per cent. This is the reason with the advent of new technologies many corporate houses decide to protect their product/process by other methods and the most common is "non-disclosure" or not to protect their IP where the new technologies have a very short span of life cycle. The most common example of non-disclosure is the case of Coca-Cola and Pepsi who have never disclosed their formulations to anyone till today. At the same time the innovative industries try to keep finding better ways to protect their IP.

Paradoxically, we are in a situation today when the market requirements drive the industry to focus on short-term results while competitor nations are making significant investments in science and technological innovations for long-term benefits. There is a strong requirement for the management of culture, which could stimulate an understanding for research related IP issues. In the coming scenario of new technologies, a number of corporate bodies have started their own R&D activities and the competitiveness of the industry is largely determined by their ability to capture the economic benefits of scientific and technological innovations through knowledge driven technologies in general and biotechnology in particular. The advent of new technologies has not only given enormous benefits to society but has also raised a number of issues in the protection of the intellectual property. Intellectual Property Rights (IPR) on inventions in biotechnology have become a controversial topic of discussion in present years, as such inventions cut across issues related to science and

technology policies, ethics and economics, etc. These issues are also directly related with the complexities of international trade. With the use of modern biotechnology many complex issues have spurred up in the IPR regime in general and patenting in particular. Several issues are indeed complex. Since the inventions in biotechnology cut across various aspects related to science & technology polices, polity of international trade, economic and ethical issues, the business methods in biotechnology have gained more complexity. Why do we have to familiarize ourselves with the science and issues surrounding modern biotechnology? There are at least two reasons. The first has to do with the potential benefits that modern biotechnology offers to humankind. The second reason why the knowledge of biotechnology is important is that with more biotechnology-derived products being placed on the market, chances are that these products will find their way into most countries, even those that do not use biotechnology for commercial purpose, but have to pay heavily due to strong IPR protection. A government needs to be familiar with modern biotechnology if it is to effectively regulate biotechnological products and ensure the effects, adverse if any, on the environment, human health, and social structures are properly managed, if not avoided. The European Commission (2002) refers to modern biotechnology as the "next wave of the knowledge-based economy" after information technology, and the "most promising of the frontier technologies."

However, developing countries should remember that the institutional and economic environment within which modern biotechnology R&D is being conducted differs significantly from that of Green Revolution technologies. The latter was essentially the prerogative of public research institutions and philanthropic foundations. In contrast, the application of modern biotechnology to agriculture is a competitive, commercial endeavor in which powerful private sector interests compete. Multinational companies in the seed, agricultural, chemical, pharmaceutical and food-processing industries play a major role in biotechnology research. Also, as a result of mergers and acquisitions in the past years, the development of new biotechnology applications in agriculture has become increasingly concentrated in the hands of a few companies. The dominant companies that currently operate within the global markets are Monsanto, Syngenta and Pioneer Hi-Bred. The Food and Agriculture Organization has pointed out that current transgenic crop releases are still "very

narrow" in terms of crops and traits and thus have yet to address the special needs of developing countries. While some 200 crops are currently under field testing in developing countries and other crop-trait combinations are being investigated, focusing mostly on virus resistance, crop quality, and in some cases, tolerance to abiotic stresses, many crops (e.g., vegetables) and traits (e.g., drought- and aluminum-resistance) important to developing countries are still almost entirely neglected. There is a strong public perception that privatisation of intellectual properties may have negative impact in all developing countries on their agriculture and healthcare sectors followed by concerns in regional food security. At present biotechnology is widely used for the manufacture of therapeutic recombinant products, diagnostic devices in animal and human health sector, genetically modified products in agriculture sector, cleaner methods of fermentation based products for industrial use, production of microbial consortia for the efficient decontamination of environment, etc. The coming scenario would further see many more new and emerging products and processes like gene therapy, creation of artificial organisms, construction of artificial genes, and many unknown things, etc.

The next two years would witness how the developing countries would deal with the definitions of patentable microorganisms, protection of other living substances, distinctions between discoveries and invention, ethical issues in biological inventions, and in the provisions for making deposits for patentable biological materials. Genetic resources are the properties of the sovereign States to which they are indigenous. Future accessions of such resources would require consent from the States. The Convention on Biological Diversity (CBD) promulgates ensuring conservation and sustainable use of biological diversity, and fair and equitable sharing of benefits from their utilization. Supply and exchange of biological materials are expected to move across the national boundaries through the material transfer agreements on the basis of authorized, mutually agreed terms among States, and subject to authorized prior consent. Consequently, access legislation and access authority for genetic materials of States would be in the making for all the CBD member countries.

Under the circumstances, a proper IPR policy thus should be in place, which should strike a good balance between the knowledge-driven technology products for the country and the industrial development issues, realising that both of them could not be independent to each

other. The IPRs are the lifeline of the R&D based knowledge-based technology industry and they encompass the right of corporate houses to have a chance of recovering their investment and have a return on capital sufficient to safeguard the interest of the stakeholders. In the emerging technologies the competitive edge will be a key driver for doing and enhancing business, whereas the competitiveness is dependent on developing new and advanced technologies. Thus, the technological innovations are facilitated by the IPRs. In a nutshell, the innovation will be the main anchor for developing competitive edge in the business with emerging technologies.

The current market size of biotechnology products is reported to be approximately US $ 1.5 billion and is expected to grow to US $ 2.5 billion by the year 2005. This estimate, however, includes hybrid seeds, tissue culture plants, fermentation derived products including antibiotics, bakers' and distillers' yeast and biological cultures. The current composition of biotech products is largely composed of therapeutics and diagnostics products for human health care, industrial enzymes and contract research services. The introduction of Bt cotton would provide fillip for the agri-biotech products further. Thus, in order to see the opportunities it is important to take cognisance of a number of global trends, viz. 70 per cent of the products under clinical testing are rDNA products or gene based products emanating from small and medium size companies; approximately 25 per cent of R&D is outsourced by drug majors. The baseline revenues of CROs in 2000 were estimated at US $ 7 billion and are growing at 30 per cent per annum. Outsourced R&D is estimated to account for 40 per cent of R&D expenditure by the year 2008. Approximately 20 per cent of the drug revenues are paid out by the drug majors as royalties on licensed products and technologies. The R&D expenditure of the top 20 pharma majors has more than doubled over the years, i.e. from US $ 20 billion in 1995 to US $ 40 billion in 2000 and it is expected to increase exponentially to more than US $ 100 billion by the year 2010. The genomics, proteomics and other informatics-based research is expected to result in an exposition in the number of these for drug discovery which will expand both opportunities and challenges for new drugs. This would dictate the focus of research to disease subsets and differentiate treatments. The big pharma majors will be forced to cut R&D expenditure and speed up R&D programmes through collaborations and contractual R&D initiatives with smaller biotech companies and CROs. There is an urgent

need to reduce drug development cost through reduction in the cost of clinical trials where countries like India and China are in a strong position to provide low cost clinical trials. With all these global factors the opportunities for the biotech business are vast which require a stronger IPR system. Apart from developed countries, the developing countries also find applications of biotechnology in diverse areas as follows:

Health care. Biotechnology can be used to arrive at novel and innovative approaches to meet the needs of society providing better immunogens, diagnostics and tools, etc., and healthcare management for ageing populations and poor countries.

Crop production. Biotechnology can deliver improved food quality and environmental benefits through agronomically and nutritionally improved crops. It may be used to produce foods with enhanced qualities like desired nutritional benefits.

Non-food uses of crops. Biotechnology can also improve non-food uses of crops as sources of industrial feedstock or new materials such as biodegradable plastics. For example, canola is now being used to produce high-value industrial oil. Under the appropriate economic and fiscal conditions, biomass can contribute to alternative energy with both liquid and solid biofuels (e.g., biodiesel and bioethanol) and processes such as bio-desulphurisation. It can provide tools for mass propagation of tree and woody species for fuel, fodder, afforestation and shelter in developing countries.

Environmental uses. New ways of protecting and improving the environment are possible with biotechnology, including bioremediation of polluted air, soil, water and waste, as well as the development of cleaner industrial products and processes like biocatalysis. GMOs can also be used in biomining, or the inexpensive extraction of precious metals from low-grade ores using microbes. Plants are also now being developed to mine precious metals (e.g., *Brassica*, which is being developed to concentrate gold from the soil in their leaves).

IPR Issues for Indian Sub-Continent

Traditionally, India is a country, which has the philosophy of making knowledge a public property.[2] This philosophy has done well to the country in general and to society in particular, in the long run by enabling access to such creations and knowledge to all without discrimination. Even in the recent times, when the whole of

industrialized countries were busy in the protection and privatization of inventions in the area of living objects/substances such as the protection of plant varieties, patenting of microorganisms and animals, such steps were generally not accepted by the developing countries including India. However, this philosophy and situations did not prevent industrial growth and prosperity in developing countries, despite the fact that they were slow for various reasons.[3] The advancement in the technological capabilities resulting in increased industrialization and with changes in international situations many countries came together and transformed GATT to WTO to include their commitments to the IPR as contained in the Agreements of WTO. Though WTO is a rule-based organisation, it encourages TRIPs plus protection of knowledge. The traditional Indian philosophy and practice in society has thus been opposite to this extreme privatisation of knowledge. Therefore, consistent with Indian culture, efforts have been made to create more room from within the provisions of the WTO to enable India to keep inventions in modern biology and biotechnology more in the public domain.

Thus, realising the potential of biotechnology and its relevance to the needs of society, the Department of Biotechnology, under the Ministry of Science and Technology, which is the nodal ministry for all policy issues, has always emphasised on the development of all facets of IPR in biotechnology. The protection of inventions through patenting or through other suitable methods has been given importance for innovations and industrial development. The Department has been instrumental in bringing together academia, industry and research institutions to work coherently for a strong IPR system in the country. Since India has been practicing conventional biotechnology for a very long time, there are many issues pertaining to unprotectable intellectual property. All inventions cannot be, or rather, should not be, protected due to various reasons because of various strategic considerations involving moral and ethical issues, e.g. inventions related to country's defence, inventions related to human and animal body, etc. However, such unprotected intellectual property would vary from country to country and a standard thumb rule cannot be framed for the same because of various degrees of distinctions between discoveries and inventions.

Generally speaking, most of the countries exclude from patenting, the discovery of scientific theories and laws, methods of performing

mental acts, discovery of natural products and processes, production of new substances with the use of biological processes, aesthetic creations, naturally occurring living substances, etc. During the last two decades or so, some countries have included patenting of many of the earlier unpatentable inventions such as microorganisms, animals and plants. The scope of ethics and morale has also been narrowed down considerably in due course of time. However, there is no uniformity in all countries, although micro-organisms are currently patentable in many countries, plant varieties are patentable or protectable under *sui generis* systems and animals are also patentable in some countries. The patentable materials for many biotech inventions are the genetic resources, which had been freely available to countries before the introduction of the Convention on Biodiversity (CBD). In the past, many such materials had freely moved across the countries. The possession by countries of such materials is neither illegal nor can laws be enacted to bring them retrospectively under the principles of sovereignty. The patenting of life forms have always been a point of concern on which the industrially developed nations thrived upon. Various milestones in patenting life in the IPR regime can be seen in Table 1.

In Indian context, the intellectual property rights including patents are granted under the sovereign prerogative of the country according to the patent law like in other countries, i.e., they are effective only in the country. *Prima facie* the patents are only granted to a process or a product (as on date, only Exclusive Marketing Rights (EMR) for qualifying products), which meets the criteria of patentability. As and

Table 1: Patenting Life: Milestones in Biotech Patent Protection

1873	-	Pasteur got US Pat no 141.072 - "Yeast an article of manufacture"
1969	-	Animal Breeding Methods - German Federal Supreme Court accepts
1975	-	Microorganisms are patentable - German Federal Court
1980	-	Microorganisms become patentable in USA (*Diamond vs. Chakrabarty*)
1985	-	Plants/tissues/ tissue culture, Seeds become patentable: US PTO
1987	-	Multicellular Organisms are patentable - US PTO
1988	-	European Patent Office grants first patent on plant
	-	US PTO issues patent on "oncomouse"
1995	-	DNA not life but chemical and patentable - EPO declaration
1998	-	Incyte Pharmaceuticals gets first patent covering ESTs
2001	-	Patent filed for 4000 human genes and proteins and codes for them by Oxford GlycoSciences
2002-03	-	The story and controversy goes on

when the information is received about patents being granted on certain non-patentable items which affect the Indian interests, the steps are taken to assess whether the grant of such patents can be challenged under the patent laws of the country concerned. As we know, there are seven areas of IPR under Agreement on Trade related Aspects of Intellectual Property (TRIPs) of WTO, viz. trademarks, trade secrets, industrial designs, copyrights, integrated circuits, geographical indications and patents. In the first six areas, Indian laws, rules and regulations, administrative procedures and judicial systems are consistent and are at par with the rest of the world. The norms of enforcement and protection proposed in the WTO are in conformity with the Indian system. However, in issues related to patents, Indian laws have been substantially different from the provisions of the WTO which have been brought in line with TRIPs with the introduction of three amendments to the Indian Patent Act 1970. The third amendment has just been made to bring in product patent to make it fully TRIPs compliant. If we look into the provisions of the WTO from the Indian Patents System (Indian Patents Act 1970), we see that they have been different in various ways as follows:

(a) WTO provides product patents in all branches of technology while the Indian Patents System provides only process patents and does not provide product patents in drugs, foods and chemicals, as on date.

(b) WTO would grant patents for any new inventions with inventive step (non obvious), capable of industrial applications (useful), whether products or processes, in all fields of technology but provide flexibility for exclusion from patentability in areas, like: (i) plants; (ii) animals; (iii) diagnostic, therapeutic and surgical methods for the treatment of humans and animals; and (iv) biological processes for the production of plants or animals. WTO, however, provides patents on microorganisms, and microbiological processes. In contrast, Indian patent laws do not allow patenting of any life form; however, patents based on microbial processes are permitted, as on date.

(c) WTO provides coverage of patent-life for all patents for a uniform period of 20 years duration while Indian system has brought it at par with WTO only recently, for processes only (including drugs, food and chemicals, which was only 7 years).

(d) WTO requires protection of plant varieties either by patents or by an effective "*sui generis*" system or by any combination thereof,

while at present there is no system for protection of plant varieties in India, despite the Plant Variety Protection (PVP) Act in place.

(e) The burden of proof in case of infringement in WTO is substantially on the alleged individual who infringes a patent, while in Indian system it is on the plaintiff.

(f) WTO does not permit discrimination between imported and domestic products while according to the Indian law, importation does not amount to working of the patent.

(g) WTO requires providing same advantage, favour, privilege or immunity granted by "a Member country" to the nationals of "any other Member country".

The IPR issues before India and the developing countries include the stand that has to be taken on the distinctions between discoveries and inventions in biological area, the definitions and the scope of patentable micro-organisms, the scope of patentability or protection of other living materials like the plants and the animals, the conditions of depositions connected with the patentable inventions involving living entities including viruses, bacteria, fungi, plasmids, genes, polynucleotide sequences with useful properties, plasmids, cosmids, vectors, gene cassettes, etc. In many of these issues, the stand of the WTO is also not clear; WTO has not made any definite recommendations in most of these facets, and the subject matter is left to speculations and conjectures to the member countries. However, the IPR issues related to modern biotechnology have been raised in a number of international forums of WTO, apart from the following:

- Convention on Biological Diversity (CBD)
- Food and Agriculture Organization (FAO)
- Organization for Economic Cooperation and Development (OECD)
- World Health Organization (WHO)
- World Intellectual Property Organization (WIPO)
- Asia Pacific Economic Cooperation (APEC)
- Office of International Epizootics (OIE)
- International Plant Protection Convention (IPPC)
- Codex Alimentarius Commission (CAC)
- World Bank

There are also a number of international agreements that relate to modern biotechnology addressing the IPR issues. The most important among these are the Cartagena Protocol on Biosafety to the United

Nations Convention on Biological Diversity and FAO's International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) apart from WTO Agreement on Trade-Related Aspects of Intellectual Property Rights

The Pharmaceutical Industry

The pharmaceutical industry has been recently in flux for allegedly placing the sanctity of patents above that of life. At such a time it is important to see that role of industry is for drug discovery and development and the IPR on medicines is the foundation on which the drug research is based. Vaccines and immunobiologicals and pharmaceutical products make a vital contribution to healthcare system. The modern drugs have contributed to increased life expectancy. The key role for the pharmaceutical industry is to discover, develop, produce and market innovative products. In view of the substantial investment and time involved to bring a drug to the market, the companies seek adequate returns on their investment. Intellectual properties are the lifeline of the research based pharmaceutical industry. They enshrine the right of companies to have a chance of recovering their investment and to have a return of capital sufficient to ensure shareholders interest. The period of market exclusivity provided by effective patent protection system is essential for the companies to sustain the vast and risky research and development investment necessary to provide new drugs and medicines and other profile actives without the patent system. Without the effective system the majority of medicines would practically perish.

Patents have attracted much of the attention for gap between rich and poor countries in access to medicine. This has exaggerated the issue of patents in developing countries, resulting in as much as 95 per cent of the WHO listed essential drugs being available off-patent. These represent a wide range of drugs to respond to most common diseases in developing countries. However, specialised drugs like that for HIV/AIDS, drug resistant tuberculosis, etc. are not accessible to the poor people. Here the ethical and moral issues in the patent system play more important role where the patent system should be applied for more societal benefits. A particular economic incentive to substantiate corporate involvement in modern biotechnology has been the granting of the patents for recombinant organisms and engineered cell lines. With the advent of rDNA technology there has been a major

reinterpretation of patenting laws all over the world, so that these days living organisms and their parts and processes, including the cells and genes of humans can be patented.

Biodiversity

The race for discovering new lead molecules has become very prominent in the drugs and pharmaceutical sector. Plant, microbial and animal biodiversities are all being mined by high throughput screening techniques for New Chemical Entities (NCEs). For example, the Himalayan yew tree has given a million dollars cancer drug, taxol. Taxol and taxol derivatives are now being mined from fungal and bacterial diversities in many parts of the world. Similarly, plant cell culture has also been successfully used to produce taxol. India's treasure in Ayurveda and Unani Medicine, which offer unique mining opportunities, further avenues for patenting of substances having larger societal importance. In accordance with the provisions of the CBD, the sovereign States have rights over their natural resources and they have the authority to determine access to their genomic resources. The CBD contains conditions for access to genetic diversity as well as transfer of technology pertaining to the biodiversity. The accesses to sharing of biodiversity are subject to prior informed consent within the national legislation and negotiations depending upon the benefits to be accrued to the donor nations. Under CBD every sovereign country needs to identify an official body that has the authority to grant access to its genetic resources and the body has to devise a mechanism for providing consent. Such mechanism should be compatible in the interacting countries so that the recipient country and the provider country can come close for the benefit of development of technologies by using natural genetic biodiversity rich in its natural form and which is not patentable through the provisions of IPR. Thus, the natural resources biodiversity is not protectable as an IPR of individuals by its mere possession under the IPR provisions of any country.

Naturally Occurring Substances

The products isolated from nature are considered as discoveries. The naturally occurring substances like proteins, glycoproteins, carbohydrates, lipids, polynucleotides, genes, DNAs and RNAs could thus be kept out of patenting which is in conformity with the provisions of TRIPs. There could be arguments in this context about how countries

would look at the discovery of natural substances or apply complex steps to purify them in a manner that does not exist in nature. Therefore, the patenting of such substances would vary from country to country.

The Government Policies in Patenting

The Ministry of Science and Technology has issued the guidelines "Instructions for Technology Transfer and Intellectual Property Rights", which would help in enhancing the motivation of scientists, research institutions and universities in various research and developent projects funded by various departments of the Ministry of Science and Technology. The salient feathres of these guidelines are as follows:

a) **Ownership of Intellectual Property:** The institution shall be encouraged to seek protection of IPR rights in respect of the results of R&D. They may retain the ownership of such IPRs. Institutions would mean any technical, scientific or academic establishment where the research is carried through funding by Central/State Governments.

b) **Transfer of Technology:** The institutions would take necessary steps to commercially exploit patents on exclusive or non-exclusive basis.

c) **Royalty to inventors:** The owner institutions are permitted to retain the benefits and earnings generated out of the IPR. The institution may determine the share of inventors and other associated persons from such earnings. However, such shares shall be limited to one third of the actual earnings.

d) **Norms for the private industry:** IPR generated through joint research by institution(s) and industrial concern(s) through joint research efforts can be owned jointly by them on mutually agreed terms through a written agreement. The institution and industrial concern may transfer the technology to a third party for commercialisation on exclusive or non-exclusive basis. The third party, exclusively licensed to market the innovations in India, must manufacture the product in India. The joint owners may share the benefits and earnings arising out of commercial exploitation of the IPR. The institution may determine the share of the inventor(s) and other persons from such actual earnings. Such share(s) shall not exceed one third of the actual earnings.

e) **Patent Facilitating Fund:** The owner institution(s) shall set apart no less than 25 per cent of the revenues generated from IPR to

create a patent facilitating fund. The fund shall be utilised by the owner for updating the invention(s), filing new patents and protecting the IPR against infringement and for building competency in the area of IPR and related issues.

f) **Information:** The institution(s) shall submit information relating to the details of the patents obtained, the benefit and earnings arising out of the IPR and the turn over of the products periodically to the Department/Ministry, which has provided the funds.

g) **March in rights:** The government shall have a royalty-free licence for the use of IPR for the purposes of the Government of India.

The Challenges for Policy Options in View of International Developments

It is a well-known fact that under the intense pressure from the US and Europe, the developing countries very reluctantly accepted to include TRIPs as part of the Agreement in Marrakesh in 1994. The most controversial aspect was the provision about patents on life forms in Article 27.3 (b) which were only agreed on the condition that they would be reviewed before they come into force in developing countries in the year 2000. The review of the TRIPs Agreement was slow in starting and has been languishing for years with a clear North-South divide producing interesting discussions but no progress. At the beginning of the review, the patenting of all living matter was the major issue and it was opined that it should be banned world over under TRIPs and any regime for plant varieties should protect the rights of farmers and local communities. Another move came from the US which proposed that no kind of inventions at all should be excluded from patenting including plants and animals, which resulted into a stalemate on the review process. In the last round of Cancun Summit, it seems that some strong efforts were made to try to get something achieved through negotiations especially on the origin of the genetic material. However, the developed countries are neither willing to make it a mandatory requirement nor to link it with benefit sharing on the issue of origin of the genetic material. A number of developing countries on the other hand are demanding for strong disclosure of origin mechanism of the biological material which would not only require detailed information about the genetic material or the knowledge but also positive proof of benefit sharing and of prior informed consent.

i) The TRIPs Review: After more than four years of stalemate between the developed and developing countries, there are signs of movement on the TRIPs Review. The discussions at WTO came out with two points, viz., one about whether patent applicants have to disclose and make public the source of the genetic material or lead on inventions involving traditional knowledge, the other point being whether and how the patent system recognises traditional knowledge in its own right. The Africa Group at WTO has added a new dimension to the debate by tabling a proposal to put traditional knowledge formally under TRIPs Rules. The policy makers in developing countries resisted TRIPs from the very outset because they saw it as a threat to sustainable development on their own terms. In fact this is correct and has now been increasingly supported by critical assessment from various UN bodies and other independent analysts as well as by growing public opinion both in North and South. Several major studies and analyses have been produced by agencies such as UK-IPR Commission, UK Royal Society, UNDP and the Human Genome Organisation which call for changes in Intellectual Property Law or limitations on its use to stop its ill effects on research, innovations and developments. It has been a wide public opinion in the developing countries that TRIPs should be amended to reduce obligations on them to adopt it in full-fledged form. It has also been opined that, at a minimum, biodiversity and traditional knowledge should be excluded from TRIPs.

ii) The "TRIPs-Plus": The European Union is aggressively forcing developing countries to adopt the strictest intellectual property rules that are possible. Since 1995 the bilateral trade agreements through which the EU seeks commitments to TRIPs-Plus standards for intellectual property on life in developing countries include Sri Lanka, Palestine Authority, Tunisia, Mexico, Bangladesh, South Africa, Algeria, and Morocco. It is aiming at more than 70 poor countries forming the Africa-Caribbean-Pacific (ACP Group). The TRIPs-Plus pertains specifically to EU-trade policy and propagates the rights of the Third World Farmers to save seeds and makes it mandatory that they must join UPOV within the next four years. Apart from EU, the US and other developed countries are also doing the same from the sides. Practically speaking the TRIPs-Plus Agreement as far as IPRs on life are concerned about implementing or joining either UPOV or Budapest Treaty, does not require patent protection of plant varieties and it does not even mention "biotechnological inventions". The TRIPs has no

provision for the member countries about implementing or joining these Agreements/Treaties. By implementation of TRIPs-Plus, the policy makers in developing countries have to align their laws with those of the EU or other developed countries so that their IPRs and patents (which are more than 95 per cent of all patents) be honoured by developing countries in order to facilitate their own market strategies and secure revenues. The large scale practice of TRIPs-Plus by the EU to implement bilateral treaties are also part of the competition with other major trade powers, namely the US and Japan giving preferential terms of business with the partner countries. The developing countries' policy makers should have a lot to put intellectual thoughts to these phenomena promulgated by the developed countries.

iii) Farmers' Privilege: The IPR applied to seeds gives breeders or whosoever that claims to have discovered or developed new plant variety, an exclusive monopoly right in relation to the seed under the Patent Laws of developed countries. That monopoly right is very strong under the Law. It will generally prevent anyone from using, producing or selling the seed without the monopoly or the patent holder's permission. In the developing countries, under the typical *sui generis* plant variety protection system, there are a few exceptions to this powerful right of the developed countries. Under this system the exception is that farmers may be allowed to save, exchange, sell or reuse part of their harvest for the next sowing season. The legal ability to reuse IPR protected seed is known as "farmers' privilege". However, this is a factual misnomer. Saving seed is as natural as eating food and this is the strength of the developing countries to produce crops of their own germ plasm. Under the Plant Variety Protection (PVP) Law this becomes a privilege to the farmers of developing countries, taken as a legal exception in the face of developed world. In developed countries, the breeders are granted the rights while the farmers are allowed to do something despite the breeders' rights for which one has to pay economic or legal consequences under the developed countries' laws. Thus the farmers' privilege should not be looked as a right in itself in the face of the IPRs applied to seeds. Tightening the loophole that allows farmers to save seeds is the easiest way to give more powers to the breeders, which should be looked into by the policy makers in the developing countries. In the international scenario of IPRs, the restrictions on the farmers in PVP Law comes in several ways often combined with other IPR Laws. For example, farmers are prohibited from saving seeds of certain crops; only certain farmers

with a specific farm size or income level can enjoy the privilege; farmers have to pay additional royalty to the breeder for any seed that they saved on the farm; the farmers can save seed but cannot exchange it; the farmers can save seeds and certain categories can be exchanged but cannot be sold; farmers can save, exchange and sell seeds but only without using the name of the variety. All these restrictions are to control the market and the competition among the seed companies of the developed countries. The *sui generis* system mainly prevalent in the developing countries should keep away its provisions from all these factors of the developed world. There are many chances that the farmers privilege would be used to strengthen the breeders rights at farmers' cost in the IPR regime.

iv) WIPO's Substantive Patent Law Treaty (SPLT): For the past more than three years a new international patent treaty under the one global patent system has been under negotiation at the World Intellectual Property Organization (WIPO) in Geneva. The SPLT aims to remove most of the national flexibility in the patent systems of the member countries and pave the way for a future world patent granted directly by the WIPO. This seems to be an appealing proposal especially for the multinational and transnational corporate houses of the developed countries like the US and EU, who view patents as the primary means to control the globalized economy. However, this global patent system does not seem to be a good omen for the developing countries and their citizens who would loose even the limited freedom left by the WTO TRIPs Agreement to adjust patent systems to national developmental goals. The policy makers in the developing countries should look to the global patent system very cautiously and can always keep themselves away from the system to stop the negotiation process. This would provide them free hand and utilization of their national patents for the benefit of the country.

v) The protection of 'undisclosed' information: Under Article 39.3 of the TRIPs, the issue of protection of undisclosed information has been often referred as "data exclusivity" by the transnational corporate houses. The matter practically relates to the marketing approval granted by the regulatory authorities for the new chemical entities. The issue of data exclusivity has never been mentioned in this article rather it refers to the undisclosed information given by the companies anywhere in the world at the time of applying for marketing approval. In most of the developing countries the existing laws take

care of the protection of the undisclosed information while the multinationals have been pressurizing hard for the implementation of the specific period of time for imposing data exclusivity, which would eventually lead to further greening of the patent beyond twenty years. This is another TRIPs-Plus issue would have lot of impact on the availability of biogenerics for the poor people of the developing countries at a much affordable and lower cost than in the developed countries. Apart from drugs, the issue is also important for the agrochemicals and transgenic crop products. The policy makers in the developing countries have to apply their minds while framing their regulations to keep out the biogenerics in general out of the data exclusivity regime.

vi) Ethical and Moral Issues: The rDNA technology has opened up more opportunities for making decisions on aspects of nature over which we previously have no decision making powers but were accepted as destiny. This technology fundamentally puts nature to a growing extent at our disposal and edges us increasingly into a technological relationship with our own bodies with non-human nature, thereby breaking down our traditional normative points of reference. The gene technology makes people more uncomfortable to cope with the dynamics of technological change creating more anxiety and uncertainties. This has led to new demands on political and other systems with more democratic control. There are questions that cannot be settled through the regulatory mechanisms of the law but call for broad debate within society as a whole. In the present scenario of technological advancements it is often argued that patenting is ethically neutral. Perhaps this argument stems from the philosophy that patenting by the inventers on the suitability of their inventions on the basis of set criteria of novelty, inventive steps and usefulness and such criteria have nothing to do with ethical issues. There are further arguments that if the practice of an inventor is considered immoral by societies, then by an Act of Law such inventions should be banned from patenting. This is what is being practiced in every society through its government legislations to prevent from patenting the inventions, the exploitation of which is against morality. Unfortunately, as on date there is no uniform universal code of conduct that can be applicable and useful for every society in the world and which can be taken as a baseline of ethics and morality. In this context of biological inventions the situation has become more complex especially for the developing countries.

Practically speaking, the ethics can change with time and with the societal needs. Similarly, the societal morals can also change with the change in time. However, at a particular time every country has the right to set the floor limits of ethics, which can be binding for the inventors over a period of time. The TRIPs of WTO is neutral in setting any limits of ethical issues, which can be globally acceptable. Therefore, it can be said that the baseline of morality can be drawn within the purview of sovereign states in accordance with their social and cultural norms and these norms should only have territorial applications. Keeping in view the Indian philosophy, which is based generally on the welfare of human and animals, it would not be an exaggeration to state that Indian ethics may be considered as baseline for the purpose of preventing inventions from patenting. Sustainability for the activities of animal welfare, dignity of human beings and preservation of biological wealth are important for the human beings. Therefore, the inventions in areas, which do not conform or are contrary to these activities, should not be considered the areas of patentability. Subsequently, discoveries of any natural element including the elements of partial or full sequence of genes from human or animals should not be allowed for patenting. Any invention leading to cruelty to animals without much advantage to the human beings should also not be permitted for patenting. Ethically speaking, all inventions employing human germ line, human embryos, the human cloning process as well as determination of sex of human foetuses should not be allowed for patenting.

Conclusions

Under the present international developments in the IPR system the policy makers of developing countries have a number of policy options for the benefit of society for safeguarding their national policies. The institutional capacities of developing countries for policy coordination across government, policy makers and the participatory process for IPR may be one of the weakest areas, which need to be further strengthened. It has been observed that in the context of the participation in international rule making, there exists lot of diversity among developing countries where some have no permanent representation and some are often with little contribution while some are mere spectators in the WTO and the WIPO Forums, in comparison to participants from developed world who are active and influential. The policy makers of such countries should be vigilant and should enhance their learning

process before it is too late. On the other hand, most developing countries face financial and human resource constraints in implementing new legislations owing to inadequate infrastructure and office procedures and they should take the help of their neighbouring countries like India.

It is important that developing countries ensure that their intellectual property legislation and procedures emphasize, to the maximum possible extent, the enforcement of IPRs through administrative action and through the existing civil justice system. They should aim to recover the full costs of upgrading and maintaining all aspects of the national intellectual property infrastructure through national IPR registration and administrative charges. Developing countries should seek to exploit the maximum possible benefits in terms of cost reduction and administrative efficiency from existing regional and international cooperation mechanisms, through various bilateral agreements in IPR especially with another developing country in the neighbourhood. Like-minded developing countries should also make concerted efforts to support high-level dialogue on new regional and international co-operation initiatives in IPR administration, training and IPR statistical data collection and management.

Developing countries should encourage policy research and analysis on intellectual property subjects in the national interest, especially pertaining to protection of plant varieties; traditional knowledge; folklore; technology transfer; etc. In order to meet the special needs of Least Developed Countries (LDCs), in developing the modern intellectual property regime and wider institutional infrastructure, there is a need for WIPO, EPO and developed countries to commit some corpus fund for technical and financial assistance. WIPO and EPO should be formally invited to join as donor agencies of the Integrated Framework alongside the World Bank, UNDP, UNCTAD, WTO, and ITC, for the purpose. It is important that WIPO makes funds available to cover the travel, accommodation and subsistence expenses of representatives from all LDC Member States to participate in all TRIPs-related capacity building projects of WTO, TRIPs Council meetings and in those meetings at WIPO which such countries are eligible to attend. It is also important that WIPO strengthen the present systems for monitoring and evaluation of its development cooperation programmes especially for the developing countries. With these efforts the LDCs

and the developing countries would be able to cope with the fast developing IPR regime where it is anticipated that the developed world would maximally utilize the resources of developing countries through various Trade Agreements of WTO.

Endnotes

1 The following online dictionaries contain further definitions of terms relevant to modern biotechnology: http://www.fao.org/DOCREP/003/X3910E/X3910E00.htm, www.hon.ch/Library/Theme/Allergy/Glosaary/allergey.html, www.sciencekomm.at/advice/dict.html.

2 This has been reflected in the ancient Indian way of life when seers preached freely and Gurus distributed knowledge through Gurukulas; where the authors responsible for many ancient creations and knowledge have not claimed their ownership or even authorship in the benefit of society.

3 India for example became capable to increase its food production significantly to about four times from the 1950s level through scientifically developing more productive plant cultivars including varieties and hybrids, and by adopting dwarf plants of wheat and rice in Indian agriculture system. The global milk production became the highest in India with the adoption of scientific techniques and with the improvement of milking animal varieties.

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