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IPR Issues in Biotechnology in the Context of Developing Countries and India*

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Intellectual Property Rights (IPR) on inventions in biotechnology may become a controversial topic of discussion in the coming years, as such inventions cut across issues related to science and technology policies, ethics and economics. These issues are directly related with the complexities of international trade. India would have to be in conformity with the provisions of World Trade Organization (WTO) on IPR in biotechnology inventions. This would require amending the present Indian Patents Act as also enacting provisions for the protection of plant varieties, besides ensuring the protection of biological goods linked with geographical indications. The position of many developing countries would be similar to India. The future 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.

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IPR and their protection in biotechnology through patenting or through other internationally acceptable laws is presently a subject matter of discussion at the national and international circles. Several issues are indeed complex. The laws of protection of biotechnological inventions in different countries are different and are not yet uniform. Member countries of WTO are to amend their IPR laws to be in conformity with the minimum provisions contained in the Trade- Related Intellectual Property Rights (TRIPS) of WTO within a specified period. The inventions in biotechnology cut across issues related to science and technology policies, ethics and economics, besides politics of international trade. Interestingly, the expectations of the world community from biotechnology are increasing fast. Societies are concentrating on the accrual of the potential and the realizable benefits from its applications in different facets of usage. Presently, the major areas of use have been the manufacture of the therapeutic recombinant products and the diagnostic devices in medical and pharmaceutical sector; the genetically modified (GM) seeds of diverse properties in agriculture; cleaner methods of production of complex fermentation based molecules for industrial use; and efficient containment of polluted environment by the use of microbial and others living biological consortia. The technology would evolve further in the coming years to register its use in many other areas presently unknown.

Public Interest Areas and Indian Government Initiatives in Biotechnology

Cost effective solutions to general public health problems would reduce health-care costs; they would also contribute to society's having more healthy people at a given time. Bacterial, viral and parasitic diseases presently contribute to major morbidity and mortality in India. With the rise in stress and strain in people emanating from rapid industrialization, increased population growth and decreased amenities for human health, there has also been a significant rise in systemic ailments such as cardiovascular diseases, diabetes, arthritis, vital organ failure and certain types of cancer. In many of these areas, solutions for protection or prolonging life are in sight through biotech solutions. These include development of vaccines, facilities for medical diagnosis followed by therapy in complex problems, development of human-body-compatible organs in animals, xenotransplantations, developing nutritious and micro-ingredients enriched food and food supplements for children and aged people, clearing up the polluted effluents and naturalizing open surroundings that have been degraded by increased human activities. In agriculture, of the various methods of increasing production, the productivity rise per unit of land use would be most significant in the coming years. GM seeds and plant cultivars are expected to contribute significantly to raising the agricultural production in the coming years. GM seeds have also great potential for producing nutritious food, the technology of which is in the developmental stage globally.

There is a strong public perception that privatization of intellectual properties may have negative impact in all developing countries on their health-care sector followed by concern in regional food security. The food security issue emanates from the control of productive seeds used in agriculture by multinational companies through IPR, accruing through their higher capabilities in research. Towards these two ends particularly, efforts should be made by India, being

the founder member of WTO[1] to shape the Indian policies to be consistent with the provisions of WTO and yet avail of maximum opportunities for the people of the country in global trade-related aspects. As India is also a signatory to CBD[2], it should ensure fair and equitable sharing of the benefits arising from the use of its biodiversity. It should further adopt means for accruing and achieving the rights of its indigenous and traditional people through newer means of IPR legislation for technology transfer in these areas. The policies to be adopted would have to ensure conservation as well as sustainable use of resources besides ensuring their fair and equitable sharing, in order to be consistent with the provisions of CBD. Use of genetic biodiversity should result in the generation of intellectual properties that should be exploited in order to provide revenues to the country.

Realizing the potentials of biotechnology and its relevance to the needs of the people, the Government of India, particularly through the Department of Biotechnology (DBT) of the Ministry of Science & Technology, have put strong emphasis on the development in all facets of biotechnology by allocating funds for the generation of skilled manpower, setting up of expensive R&D infrastructure, providing R&D supports for sophisticated research in all the relevant areas, supporting entrepreneurs for setting up biotech industries through statutory procedures and by formulating policies conducive to the faster public and private sector investments in biotechnology in the country. The DBT had spent[3] Rs 8.01 billion during the period 1987-88 to 1997-98 for the development of all aspects of biotechnology in the country. The expenditure on R&D out of this was 65.7%, that for infrastructure and institutional development was 25.6%, while on the human resource development it was 8.7%. Expenditure during the same period by all other agencies including the private sector was about Rs 0.35 billion. The total expenditure by the country on biotech development was therefore about Rs 8.36 billion, which is considered sizeable, compared to the expenditure made in this area by many other developing countries.

Unprotected Intellectual Property

Protection of inventions through patenting or through other suitable methods is considered to be important instruments for innovation and industrial development. The segments, namely the government, the industry, the R&D institutes including the universities, the political system and the public are to work together to assist any country to frame laws relating to the protection of industrial property to strike a balance between privatization of inventions to reward the inventors, and concurrently to provide protection to public interest factors which in certain situations should be of paramount importance and should take dominance over inventors' interest. All inventions cannot be or should not be protected due to various reasons such as strategic considerations (invention related to countries' defence, etc.) or due to other reasons such as those areas which are contrary to morale or ethics (invention related to human body, cruelty to animals, etc.). Reasons for categorization of such areas vary from country to country, and cannot be universalized. Moreover, countries usually make different degrees of distinctions between discoveries and inventions. Generally, all countries exclude from patenting, the discoveries of scientific theories and laws, methods of performing mental acts, all kinds of magic, mere discovery of natural products and processes, pro-

duction of new substances by using essentially biological processes, aesthetic creations, carrying on or performing business by various complex but innovative methods, and usually all novel processes the applications of which produce better or economically more valuable living objects. Presently, during the last 18 years or so, some countries have included patenting of many of the earlier excluded patentable invention such as patenting of microorganisms, animals and plants. The scopes of ethics and morale have also been narrowed down considerably. Not all countries have yet taken a uniform position, although microorganisms are currently patentable in many countries, plant varieties are patentable or protectable under *sui generis* systems and animals are patentable in some countries. The source materials for many biotech inventions are the genetic resources, which had been freely available to countries before the introduction of CBD. Many such materials had freely moved across the countries in the past. Their possession by countries that are non-indigenous to such materials is neither illegal nor can laws be enacted to bring them retrospectively under the principles of sovereignty.

WTO and Transition Period for Enactment

With the introduction and adoption of the provisions of the WTO in April 1994, signatory countries had agreed to enact the provisions of WTO within a period of time (5 to 10 years from 1 January 1995) so as to enable the world community to harmonize the IPR protection laws. The developing countries, which do not currently provide product patenting as in India, will have an additional transition period of 5 years to apply these provisions.

Minimum Provision for IPR Protection under WTO and Existing Indian Laws

The seven areas of IPR under TRIPS are trademarks, trade secrets, industrial designs, copyrights, integrated circuits, geographical indications and patents. In the first six areas, Indian laws, 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 WTO are in conformity with the Indian system. In the last area, namely in issues related to patents, Indian laws are, however, substantially different from the provisions of WTO in the following way: [4]

(i) WTO provides product patents in all branches of technology while Indian patents system does not provide product patents in drugs, food and chemicals, but provides only process patents.

(ii) WTO would grant patent for any invention (whether products or processes) in all fields of technology provided they are new, involve an inventive step (non-obvious) and are capable of industrial applications (useful), but provide flexibility for exclusion from patentability in areas like: (i) diagnostic, therapeutic and surgical methods for the treatment of humans and animals; (ii) plants; (iii) animals; and (iv) essentially 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.

(iii) 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.

(iv) WTO provides 20 years uniform duration for coverage of patent life for all patents while Indian system provides 7 years for drugs, food and chemicals and 14 years for others.

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

(vi) 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.

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

(viii) Compulsory licensing is permitted on merits of each case in WTO, and the holder of patent will have to be heard, but Indian law provides compulsory licensing in the case of food, pharmaceuticals and chemical sector. Interpretation of Indian law implies that compulsory licensing would be freely available in these sectors.

Convention on Biological Diversity

In accordance with the provisions of CBD, the States (sovereign countries) have rights over their natural resources and they have the authority to determine access to their genetic resources. Article 15 and Article 16 of CBD contain conditions for access to genetic resources, and conditions for access to and transfer of technology respectively. Access to and sharing of biological diversity are dealt within the documents of CBD on mutually agreed terms and are subject to prior informed consent, but would be subject to national legislation. Consequently, access to genetic resources has to proceed by negotiations and it has to decide the form in which the benefits are to be accrued to the donor country. Sovereign countries or national governments are required to take legislative, administrative or policy measures to achieve "access to and transfer of technology" between the recipient and supplier, for genetic resources. Obviously such policy measures would have to deal with private sector also, as technologies are expected to be developed more within the ambit of private sector than the public sector. In complying with these provisions of CBD therefore, every sovereign country needs to identify an official body that has the authority to grant access to its genetic resources and further, that body has to devise a mechanism for providing consent. Such mechanisms would have to be compatible so that the recipient country and the provider country can come closer for easing the development of technologies by using natural genetic biodiversity, which in its natural form is not protectable as intellectual property through the provisions of IPR. Natural genetic biodiversity is not protectable as intellectual property of individuals by its mere possession, under the provisions of IPR of any country.

Discussion

The issues before the country include the stand that would have to be taken on the distinctions between discoveries and inven-

tions in biological area, the definitions and the scope of patentable microorganisms, the scope of patentability or protection of other living beings like the plants and the animals, the conditions of deposition connected with the patentable inventions involving living entities including viruses, bacteria, fungi, plasmids, genes, stretches of polynucleotide sequences of useful properties, plants, animals 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. The CBD document has not provided definite guidelines for access and exchange of biological materials among States. Consequently, CBD Member States would have to frame their access legislation and would create their biological materials access authority. Such authorities of States would have to promulgate terms that ensure conservation and sustainable use of biological diversity on one hand, and fair and equitable sharing of benefits from their utilization among member countries on the other hand.

India is a country, which is philosophically wedded to the concept of making knowledge a public property. This has been reflected in the Indian way of life where the authors responsible for many ancient creations and knowledge have not claimed their ownership or even authorship. This philosophy has done well to the country in the long run by enabling access to such creations and knowledge to all without discrimination. Even in the recent times during the last 40 years, while 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. But these positions did not prevent growth in prosperity in developing countries, though they were slower (for various reasons). India, for example, was able to increase its food grain production significantly by about four times from the 1953-1954 level by scientifically developing more productive plant cultivars including varieties and hybrids, and by adopting dwarf plants of wheat and rice in Indian cultivation. The global milk production became the highest in India by the adoption of scientific techniques for the improvement of milching animals. Even in the drugs and pharmaceuticals area there had been impressive progress both in the production of bulk drugs and finished formulations; India became the strongest among the developing countries in having a large local base of basic production of the largest number of bulk drugs. The country adopted such strategies as to bring in greatest competitiveness in the market place that resulted in India's having the lowest prices of pharmaceutical formulations in the world. But with the advancement in the technological capabilities resulting in increased industrialization and with changes in international situations, many countries came together and became members of WTO, thereby reinstating their commitments to the IPR as contained in the documents of WTO. WTO encourages privatization of knowledge. The prevailing Indian philosophy and practice in society is just opposite to privatization of knowledge. Therefore, consistent with Indian culture, efforts have been made to create more room from within the provisions of WTO to enable India to keep inventions in biology more in the public domain.

Microorganisms

TRIPS would require the protection of microorganisms. The present Indian Patents Act does not allow the patenting of any life form; this act will now be modified to extend its scope to include the patenting of patentable microorganisms.

Microorganisms as per the classical definitions are organisms too small to be visible to the naked eye; organisms include all the living entities, which may be a single cell or a group of differentiated but interdependent cells. Microorganisms include viruses, bacteria, actinomycetes, yeast, fungi and protozoa.

Ordinarily microorganisms do not include various tumours forming cell lines and monoclonals and these are not natural organisms but are produced under abnormal stress conditions or under human interventions. Moreover, most of the transformed cell lines and all the monoclonals are derived from cells/tissues of vertebrates. Vertebrates are not considered as microorganisms. Therefore, one view could be that while considering the ambit of microorganisms the cells and the tissues of higher life forms including vertebrates and non-vertebrates may be kept out from within its scope. From this point of view, the microorganisms would be the organisms of lower life form which cannot be differentiated by naked eye, that are self- replicable entities or which replicate via a host organism. Microorganisms would include viruses, sub-viral agents, plasmids, and bacteria including cyanobacteria, actinomycetes, yeast, fungi and protozoa. They would not include cell lines of vertebral or other cell lines originating from higher life forms. They would not also include monoclonals derived from vertebrates.

The other view on the microorganisms may be to include all microbial entities that have self-replicating capacities. Such a definition would include the cell lines obtained from higher life forms, including the monoclonals derived from vertebral cell lines. Interestingly, such a definition would include even the plants and animals as microorganisms up to the time the embryos are dividing and moving towards the development and differentiation into specific organs, but are small enough to be visible to the naked eye, provided that the stages up to which they may be so named could be made stable by some methods. Unnatural vertebral cell lines are however essentially stable cell lines. In essence, this view would deny the exclusions available to countries for the patenting of animals and plants under Article 27 of TRIPS.

It is suggested therefore that countries could keep the core issue of defining microorganisms away from the scope of TRIPS in future discussions of WTO. The definitions could be handled in the national laws.

Many countries have considered naturally occurring microorganisms as non-patentable. But presently the developed countries including the European Union, Japan and USA have started sharing the view that if naturally occurring substances including microorganisms are isolated for the first time in a form or purity that did not occur in nature, if they were identified distinctly and if they had industrial applications, then these would be the subject matter of patents. The demarcation of the products of nature and the inventive steps leading to innovative products not found in nature has been demolished in such a treatment. Such a treatment of naturally occurring substances does not distinguish between "discovery" and "invention". Therefore, instead of imposing

such a treatment on other States, it would be wiser to hold that it should be left to countries on how they would like to treat naturally occurring substances. This view is consistent with TRIPS.

Within the ambit of the provisions of WTO, the patentable microorganisms could be considered to be those that have been produced by human interventions, where the interventions are non-obvious and further that they do not involve an essentially biological process. Such microorganisms would no doubt satisfy the criteria of novelty, inventive steps and usefulness or industrial applications. Such patentable microorganisms may include the transgenic viruses, sub-viral particles, plasmids, bacteria, actinomycetes, yeast, fungi, and parasites. They would not include the tumour forming cell lines and the monoclonals derived from vertebrate cell line or other cell lines originating from higher life forms.

The exclusion criteria for the purpose of patenting mentioned to define patentable microorganisms would be helpful to the developing countries to build innovations based on many useful cell lines, which could be kept in the public domain by such treatments. Once a microorganism is patented, it would not be publicly available within the protected period, without exploiting the patent.

Naturally Occurring Substances

The present Indian Patents Act does not allow patenting of products *per se*. Product patenting is a part of the requirement of TRIPS. Patentable products must satisfy the criteria of patenting, however.

Natural products isolated from nature are generally considered to be the products of nature; their isolation, identification, characterization, indexing and finding their uses including new use are considered as discoveries. There could be arguments in this context ranging from how countries would look at them from the simplest case of their "mere possession" to the complex steps of applying human ingenuity to isolate them in pure forms that did not exist in nature. There are no guidelines in the documents of TRIPS on treating these issues. Therefore, whenever member countries would be adapting to the floor limits of conformity of the provisions of TRIPS in their national patent laws, it is for them to decide how they would be looking at naturally occurring substances. As argued earlier, if it is accepted that there is wisdom in keeping the national patents laws more public friendly, decisions could be taken to treat all the naturally occurring substances, howsoever isolated or processed, to be kept outside the purview of patenting on the arguments that such products are mere discoveries. All natural products such as proteins, glyco-proteins, lipids, phospholipids, fats and oils, carbohydrates, simple chemicals, agro-chemicals, glandular products, botanical pesticides, polynucleotide sequences, naturally occurring genes, all naturally occurring DNAs and RNAs could thus be kept out of patenting in countries' own patenting laws. This position is consistent with the provisions of TRIPS.

Plants and Plant Varieties

The Indian Patents Act does not permit the patenting of either plants or plant varieties. The provisions of TRIPS require that plant varieties need to be protected either by patenting or by a *sui generis* method or by a combination of both, but countries could keep plants outside the purview of patenting. Patents on plants are obtainable in certain developed countries like USA, Japan and

Australia under certain conditions. But the patent laws in Europe exclude plant varieties from patenting; indeed plant varieties are protected by *sui generis* method.

In Europe, the plant variety protection has been given a separate legal system of protection, commonly known as Plant Variety Rights or Plant Breeders' Rights. Such rights originated from and through the enactment of the International Union for the Protection of New Varieties of Plants (UPOV). The UPOV has presently membership of 43 States, and many countries for protecting plant varieties have accepted its 1978 version. However, UPOV had come out with its 1991 version that came into force from April 1998. Many countries had not yet ratified the 1991 version of UPOV. The 1978 version of UPOV dealt with the Plant Breeders' Rights for commercial marketing of the reproductive parts of the protected plant varieties. The researchers as well as the plant breeders could use such protected varieties as study materials for further research, and the resulting new varieties developed from the protected varieties did not require authorization for the subsequent breeders or the researchers to utilize them for commercial gains. These rights had been withdrawn in 1991 version of UPOV. Further, the 1978 version of UPOV provided the farmers' rights to save seeds in accordance with their traditional practices. This right had also been substantially curtailed in the 1991 version of UPOV, on the grounds that farm-saved seeds could form a sizeable part of the annual use of seeds of protected varieties; therefore if farmers were allowed to save seeds, the saved portion would collectively form a substantial quantum that would result in loss in revenue of the owner of the protected variety. The 1991 UPOV allows the farmers to save limited quantities of seeds for their own requirements only.

The TRIPS does not mention about or refer to the provisions of UPOV, nor does it indicate the precise steps to be taken for protecting plant varieties, except that it promulgates that plant varieties are to be protected. India is not a member of the UPOV. India is therefore; free to enact its own Plant Variety Protection (PVP) law that would be consistent with the TRIPS. While framing its PVP, India can draw from the provisions of UPOV, especially from its 1978 version. In the new law the farmers' rights as well as the researchers' rights could be upheld in accordance with the traditional practices of the country. The researchers' rights are consistent with the provisions of intellectual property principles in any country that research could be carried out with any material, provided that any new material produced out of the utilized material (protected or unprotected) is not marketed. In order to market a new material produced from a protected material, there may be need to obtain the consent of the owner depending upon the IPR laws of the States.. As regards farmers' rights of saving seeds, these have to be consistent with the traditional practices of the country, on which TRIPS cannot have any control. India can, therefore, draft its own PVP law that can have adequate provisions for protecting the farmers' rights as well as the researchers' rights.

A plant variety is identified by its whole genome. The usual criteria of protection through UPOV Convention is available to new varieties of botanical genera and species, provided the variety is clearly distinguishable (D) by one or more characteristic features from any other known variety, the new variety is sufficiently homogeneous or

uniform (U) having regard to the features of its vegetative propagation or sexual reproduction, and further the new variety is stable (S) in its essential characteristics. This implies that it should remain true to its description after repeated propagation or reproduction or at the end of each cycle where the breeders have defined a particular cycle of multiplication or reproduction. Popularly, these criteria are called as DUS criteria. All member countries can adopt these criteria. The phenotypic characteristics are to be identified, indexed and notified in accordance with these criteria. Concurrently it would be most useful to introduce genotypic identifications, which would no doubt include characteristic RFLP, RAPD and DNA finger printing procedures for bringing in more preciseness to identification. Genotypic characterization would, however, require the creation of enormous infrastructure in the government laboratories. A national laboratory may therefore be designated and equipped for this purpose to augment capacity building within the country.

In India, the Protection of Plant Varieties and Farmers' Rights (PPVFR) Bill, 1999 was introduced as Bill No: 123 of 1999 in the Parliament. The Bill is under examination by a Select Committee of the Parliament. The Indian PPVFR has substantially incorporated in it the 1978 provisions of the UPOV; the criteria for the protectable plant varieties are similar. The varieties that would be developed by incorporating one or a few transgenes by standard methods would be considered as essentially derived varieties and these would also be eligible for protection as "essentially derived varieties". In other words, GM plants shall be protected as essentially derived varieties provided they satisfy the DUS criteria. The PPVFR recognizes the Researchers' rights as well as the Farmers' rights, similar to what was available in 1978 UPOV. The Bill further recognizes the rights of the Community that contributed to the development of a protected variety. The details of the adopted PPVFR will be known only after the Bill is accepted by the Parliament, and is enacted.

Animals and Animal Varieties

The TRIPS has provided exemptions to countries to the protection of animals. Animal varieties are included within the broad provisions of animals. Consequently, the opportunity provided in the provisions of WTO should be availed of and animals including animal parts like organs, tissues and cells of animals modified to patentable invention may be kept out of patenting, as this would enable the people to use inventions in them freely for benefits.

Interestingly, animal breeds produced by any country by using traditional methods are not protected through any law anywhere in the world. Traditional methods include the biological methods of animal breeding. However, if novel animals are produced by non-biological, non-naturally occurring processes such as by full genomic cloning as is done in the development of Dolly [12] or by touching the germ cell lines[13-15], introducing in them new genetic traits then the resulting animal as well as the processes could be patentable in accordance with the laws of some countries. The transgenic onco-mouse developed by the Harvard College of USA[16] was assigned a US patent protection as the animals qualify all the criteria of patenting. Following the decisions of the US Patent Office, a European Patent was also granted, but the Animal Rights Group of Europe opposed the grant of such a patent; the matter is consequently sub-judice in Europe at the

present. The moot point in such patents arises from ethical issues of patenting animals, which will be discussed later on. The take-home lesson is that developing countries like India could keep the patenting of animals and animal varieties, how so ever derived, outside the scope of their patenting laws, which position is consistent with the provisions of TRIPS. It can also be argued that while efficient animal breeds produced by traditional methods have made phenomenal progress the world over, the science or the technology applied to animal breeding has not suffered due to lack of patenting process in them. It can also be stated that non-availability of the system of patenting or any other method of intellectual property protection in this area has not affected its scientific or technological developments. Why therefore shall a system be brought in place in this area that can restrict the free availability of superior animal breeds to any country? On the contrary market forces and market competition should be allowed to bloom, as such measures ensure to the maximum the interests of the consumers.

Process Patents/Innovative Reverse Engineering

The Article 28 of TRIPS confers certain rights on its owner, according to which the owner can prevent third parties from making, using, offering for sale, selling, or importing for these purposes, the product that is patented. If the subject matter of the patent is a 'process for making a product', the owner shall have the right to prevent third parties from using the process for the above purposes .In accordance with Article 34 of TRIPS the burden of proof in respect of infringement of the rights of the owner even for a 'product by a process' patent is on the alleged infringer. Therefore, in the ensuing patent regime of TRIPS innovative new processes would have to be developed for making a product that is protected by a process; unless the new process is substantially innovative, it would not be easy to introduce "products protected by a process" by other entrepreneurs from the member countries in the coming years.

Geographical Origin of Biological Materials and Traditional Knowledge

Every country is endowed with natural biological resources. CBD states that technology transfer should be carried out on terms, which are consistent with effective protection of IPR. It further recognizes that patents may have an influence on the implementation of the provisions of CBD, and therefore patentee should cooperate in this regard subject to national legislation and international law in order to ensure that such rights are supportive, and they do not run counter to the objectives of CBD. Biological inventions are expected to draw heavily from genetic resources. Consequently, in order to facilitate the claim of individual countries on such genetic resources, it would be essential to legislate that inventors would have to disclose in their patent specification the source of the biological materials used in the inventions. These are consistent with the provisions of TRIPS, which in its preamble on TRIPS states the need to promote effective and adequate protection of IPR and to ensure that measures and procedures to enforce IPR do not themselves becomes barrier to legitimate trade.

There are also situations where inventions would emanate from traditional practices or from established traditional products used locally. For example, there are innumerable local food and beverage as well as local remedies, which are standardized by using

the methods of fermentation or extraction or processing in traditional manner. Documents of invention originating from the use of such materials or processes should describe in sufficient details such starting materials including the traditional practices, with a view to enabling the governments to take such steps in future as would be deemed fit to benefit the communities holding such knowledge.

Further, there are already several traded goods that originate from specific geographical locations. Such goods when marketed with mark (similar to labelling) or geographical indications of origin are expected to fetch better prices in the trade because of established goodwill of such products. Provisions exist in Article 22 of TRIPS to apply geographical indications on such goods to enable procuring premium on them when traded. False claims should be subjected to prosecution and punishment. Examples of biotech goods in relation to geographical indications in Indian context are Darjeeling tea, *basmati* rice, Hyderabadi *biryani*, Bangali *rasogulla*, Mysore *pak*, Gujarati *dhokla*, *petha* of Mathura, Burdwan's *mehidana* and *sitabhog*, Bongaon's *kancha golla*, Bikanari *bhujia*, *ktung rymbari* and *dohkha pdem* of Meghalaya, *hawaigar saidan* or *saibum* of Manipur, *khorias,bastenga, gundruk, laitenga, hajpani, para-apong, sulai, zu* and *phatika* of Assam. There are many other such local foods of popularity in different parts of India. Like India, every country has some such speciality items of agricultural, natural or manufactured goods. In order to exploit the names of geographical indications on goods for obtaining a premium, Member Countries are entitled to institute national laws consistent with the provisions of WTO to register such products under the provisions of geographical indications as intellectual properties, and would be entitled to collect revenues from the registration of such marks. Such revenues collected by the States can then be spent for the upliftment of the communities from where the geographical indications originated.

In India, the first step towards these directions has been taken by enacting The Geographical Indications of Goods[17] (Registration and Protection) Act, 1999. The rules and procedures for enacting this would soon be notified. According to the Act, "geographical indications" in relation to goods would mean an indication which identifies such goods as agricultural goods, natural goods or manufactured goods as originating or manufactured in the territory of a country or of a region or locality in that territory, where a given quality or reputation or other characteristics of such goods is essentially attributable to its geographical origin and in case where such goods are manufactured goods one of the activities of either the production or of processing or production of the goods concerned takes place in such a territory, region or locality , as the case may be. Goods would mean any agricultural, natural or manufactured goods or goods of industry and includes foodstuff. The Indian Controller General of Patents, Designs and Trade Marks shall be the Registrar of Geographical Indications. The use of a geographical indication shall be construed as a reference to the use of a printed or other visual representation of the geographical indication.

Ethical Issues

Patenting of invention confers rights on the patent holder to prevent others from exploiting the invention for commercial gains. It is a right conferred by the sovereign States to the owner. The State machinery guarantees such rights to the inventors. Consequently,

patenting rights are powerful rights conferred upon the patent holders. As the States deal with the welfare and equity of people, all acts of States are to be ethical. Consequently, the patenting laws in every country have ethical considerations, and inventions that cut across the questions of morality are not allowed to patent. In the existing Indian Patents Act, provisions have been built in for preventing patenting of inventions that are contrary to public morale. The European Patent Convention (1973) in its Article 53(a) excludes from patenting any invention "the publication or exploitation of which is contrary to morality or *ordre public*". All European countries have incorporated this provision in essence in their national patent laws. Subsequently, European Parliament and the Council on Legal Protection of Biological Invention issued[18] Directive No. 98/44/EC on 6.7.1998 for patenting of biological inventions.

It is often argued that the acts of patenting are ethically neutral[19-21]. Perhaps these argument stems from the philosophy that patenting attorneys who advice inventors on the suitability of their inventions examine the cases on the basis of set criteria of novelty, inventive steps and usefulness (industrial applications) only, and such criteria have nothing to do with the ethical issues. Some people argue that if the practice of an invention is considered immoral by societies then by an act of law such inventions should be banned from patenting, and consequently nobody would bother to patent such inventions. Indeed, this is what every society does through its governments to prevent from patenting the inventions the exploitation of which is contrary to morality or to the *ordure public*. Unfortunately, there is no universal code of conduct that is applicable and useful for every society uniformly that sets the baseline of ethics and morality. In the context of biological inventions, the situation has become more complex especially for the developing countries after Chakrabarty[22] was allowed a patent on his invention of a genetically modified *Pseudomonas* microorganism that had an additional plasmid incorporated by Chakrabarty, by virtue of which the organism had acquired the capacity of metabolising a wide range of hydrocarbons. The importance of this patent was that living objects that could not hitherto be patented became patentable from this time. Societies took a long time to accept that this patent was not a patent for life *per se* but for a living organism that was "partially modified" by the inventive genus of human interventions. In fact, Chakrabarty's invention did not create any new life but it only modified irreversibly a life form that did not exist in nature. The modification was, however, very powerful and the progenies of the modified organism also inherited the modified properties intact. Hereafter, patenting of complex living objects have been allowed such as the patenting of other microorganisms and hybridomas and many cell lines derived from higher life forms such as insects, mammals, etc. US have allowed the patenting of an oncomouse[16], which is an animal that can be used for testing the carcinogenic potential of new compounds. The ethical considerations in the patenting of these inventions have, therefore, changed and living objects have not been considered as a bar for their being patented. The moot point, therefore, in the consideration of ethical issues from these experiences are clear that the floor limits of ethics can change with time and with the societal needs. Ethical issues are, therefore, to be considered as dynamic societal morals that can change with time. However, every country at a particular time has the right to set the floor

limits of ethics that can be binding within the territory over a period of time. WTO is neutral on setting any floor limits of ethical issues that are globally acceptable. In this context, therefore, it can be stated that the baseline of morality should be drawn within the States in accordance with their social and cultural norms, and these norms should only have territorial applications.

With the above in view, it is stated that for India a philosophy based on general welfare of human and animals should be considered as the base line of ethics for the purpose of preventing inventions from patenting. Maintenance of activities of animal welfare, human dignity and preservation of natural living biological wealth are natural to human beings. Inventions and activities, which are contrary to these, would trade upon ethical issues. Therefore, inventions in areas which do not conform to animal welfare or which bring down human dignity should not be considered to be areas that are patentable. Consequently, discoveries of any of the natural elements including the partial or full sequence of genes from human body should not be allowed for patenting. All inventions leading to cruelty of animals without bringing about any advantage to knowledge or information or welfare or medical benefits to human or animals should also not be allowed to be patented. Similarly, process for modifying human germ line, methods of determining the sex of human foetus, use of human embryos for organ culture and cloning of human beings should also not be allowed to be patented.

Discovery and Invention

All findings in biology where a biological substance or its properties already existed in nature but was noticed for the first time individually or collectively by human should be termed as discovery. This shall apply to microbes, plants and animals including every substance in them in full or in parts of their development in the natural form, in the biological system. Naturally occurring microbes, plants and animals, naturally occurring biochemicals, genes, nucleic acid stretches, proteins, carbohydrates, lipids or combinations thereof which are naturally occurring, should be termed as products of nature and they should be kept away from intellectual property protection. Properties of such substances as well as the inter-relationships and functions should be considered to be falling within the preview of natural laws, and therefore finding them by human even for the first time should be considered as discoveries. Inventions on the other hand would be those findings through human intervention which did not occur naturally but could be made to occur by human intervention, and therefore which would satisfy the criteria of intellectual property protection namely being new, involving inventive steps and being useful or having applications. The usefulness or applications are in relation to industrial applications. Consequently, patentable biological substances should have industrial applications at the time when they are considered for protection and should not be based on hypothetical or potential future applications.

All process of multiplication and production of animals and plants by natural processes such as crossing or selection should be considered as essentially biological process and should not be considered as patentable invention.

Deposit and Access of Biological Materials

Two hidden criteria for the protection of IPR consist of adequate description of the inven-

tion and the reproducibility of the invention in the hands of persons reasonably skilled in the art. In biological invention, it is not possible to adequately describe the living substance(s), nor it is possible to reproduce the invention without the biological material(s). Consequently, the world community has accepted that all biological materials be deposited in recognized international repositories. In accordance with the Budapest Treaty [23], patentable microorganisms are required to be deposited by the inventors in designated recognized repositories. Such provisions are required to be legislated by the States for all biological materials including plants, animals and multiplying substances such as genes, plasmids, viruses, etc. as is applicable for microorganisms. These may require the creation of national depository set-ups and the building up of the necessary capabilities in many States. Besides, States may also become a part of the Budapest Treaty by complying with the necessary procedures for enabling them to have access to deposition of biological materials in designated labs for the purposes of their IPR.

Conclusion

The protection of plant varieties to individuals in Europe in sixties through UPOV was the beginning of conferring rights of living substances / materials /objects to individuals. The US decision to allow Chakrabarty to obtain a patent on his genetically modified *Pseudomonas spp.* was another landmark event that started the world community to prepare it for accepting the patenting of complex and higher life forms including hybridomas, vertebral and insect cell lines, genetically engineered plants and animals in the developed countries. Although the developing countries resisted to such IPR in their own patenting laws initially, the trend is fast changing. Patenting of living organisms that qualify the criteria of patentibility are being given protection through their national laws in many developed countries and the debate on whether living materials can be patented is gradually being pushed to backseats. Realizing that this compromises ethical issue at least for higher life forms and having regard to the fact that the research capability of developing countries are lower and would continue to remain so for many years in future, it is prudent to conclude that liberal views on patenting of living organisms would mainly benefit the developed nations. There is wisdom in taking advantage from within the provisions of WTO to keep out of patenting as much of invention in living objects as is possible by the developing countries within the framework of WTO in their national patenting laws. It would be prudent to tackle the issue by creating conditions of strong market competition within the territories of States by providing equal level playing grounds in other facets and factors of production so that only the fitter enterprises could sustain in competition. The bargaining point of the developing countries lies in having their large local markets, which would grow over the years irrespective of what laws of IPR they would adapt.

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. CBD promulgates ensuring conservation and sustainable use of biological diversity, besides fair and equitable sharing of benefits from their utilization. Having abundant natural resources, the developing countries have an edge over the developed nations. It makes good sense to create conditions of structured but compatible mechanism of

sharing of such resources with other countries or individuals; sharing is expected to promote finding ways of quicker exploitation of such resources. Once the resources are put to commercial use, the countries sharing their indigenous genetic resources would be able to receive part of the tangible wealth created through their exploitation. Supply and exchange of biological materials are therefore expected to move across the borders through the materials transfer agreements on the basis of authorized, mutually agreed terms and subject to authorized prior informed consent. Consequently, authorities and legislation for the access of biological materials of States would be in the making for all the CBD Member countries.

The benefits from the application of biotechnology are fast penetrating into the societal fabric of every country. The areas to be demarcated as unprotectable intellectual properties in modern biology would become a subject matter of discussion and it would not be easy to come to consensus. IPR laws of the Member Countries of WTO including India would have to be in conformity with the provision of WTO. This would require amending the IPR laws of States; in many States some laws are to be enacted for the first time such as PVP laws and laws on geographical indications. The future years would witness how the developing countries including India would deal with the issues of patentable microorganisms, protection of other living objects/substances, ethical issues in biological inventions, distinction between discoveries and invention, farmers' privilege, researchers' rights, community rights, geographical indications, methods of sharing of biological materials and in creating provisions for making deposits for IPR protected biological materials.

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