

# Intellectual property and protection of right in biotechnology

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*The remarkable advance of modern biology has resulted in an impressive list of products and processes of direct benefit to man, and promises much more. It also raises political, economic, ethical and philosophical questions concerning patent law.*

Intellectual property arises from some new knowledge of some value to many in society at large. Such knowledge may be in the form of a literary work, a musical composition, a new arrangement or design or assembly of known components, a new product, a new method or process of making a product, a new combination or formulation with better effects made from known ingredients, a measuring or display device, or a control system or programme for analysis and management. Protection is granted for copyright of printed or recorded material, a new product, a new process, a design or a trademark. Such protection ensures identity.

Protection against copying is possible for products such as a pharmaceutical mixture, a perfume and a food preparation through maintaining the information on exact composition or method of preparation secret or by use of secret ingredients. Other methods are by rendering copying or propagation impossible: sale of fertilized eggs or only female birds or only hybrid seeds, or careful control and destruction of microbial strains of industrial fermentation and microorganisms for antibiotics. Patents on products, designs or processes offer protection for a limited period provided full disclosure of the nature of the invention is made. Copyrights on drawings, patents on products, processes and designs, and registration of trade marks pertain to industrial intellectual properties.

## Characteristics

Laws on intellectual property rights are national laws and differ from country to country. By historical convention, no distinction is made in any national laws

concerning rights to citizens with regard to property rights in this area, unlike those laws relating to residence, ownership of physical assets or shares in companies, or employment.

Intellectual property rights are also modified in the same country from time to time. These changes arise from recognition or derecognition of certain products, such as drugs and pharmaceuticals, foods, pesticides, agrochemicals, enzymes, antibiotics and other chemicals, as qualifying or not for patents. There are also differences in period of protection. Some countries have provisions by which non-use of an invention for manufacture in the country within a specified time renders the patent invalid, since the aim of the patent should be to protect manufacture by the owner or a licensee and not prevention of local production. In some countries, it is possible for governments to have rights of manufacture in the public interest.

New patenting principles are also emerging in respect of design patents. A few developed countries are granting patents for semiconductor electronic assemblies made from known components that can be purchased. Others regard such assemblies as mere arrangements and not sufficiently original to merit patent protection. Electronic microprocessor controls are not invariably patentable in all countries. This is a subject of international debate and negotiations presently.

Copyright provided for books, periodicals, films or recorded music is now sought to be extended to all computer software. Here, again, there are different perceptions. Copying of articles from scientific journals for personal or group use and translations may be regarded as infringements.

Trade marks provide an identity for constant quality, performance and uni-

formity of products from a manufacturer or trader. While most countries permit registration of foreign and international brand names, some do not allow their use on items manufactured within the country. Such brand names may provide undue and unfair advantage over locally designed products in local markets and may preclude export of products with foreign brand names.

## Concerns

Attention to intellectual industrial property rights has increased sharply owing to increased international transfer of technology and international trade as well as the very high costs involved in successfully developing and marketing new products and processes. Global telecommunications and advertising in mass media at great expense provide high level of recognition of brand names across national boundaries. The ability to copy products and processes in many countries and companies in a very short time and the advances in information technology have caused concern among the original inventors, who are anxious to obtain global protection rights. At the same time, there is concern that the fruits of advances in science and technology should not be denied absolutely or made excessively expensive for application in the mitigation of hunger, poverty, disease, malnutrition and human suffering in developing countries, which account for four-fifths of the world's population.

Many poor countries are unable to purchase adequate numbers of scientific and technical books and periodicals or sophisticated measuring and scientific instruments for teaching, research or quality control. Qualified and motivated

teachers, scientists, engineers and technologists are not able to perform efficiently in such countries owing to the high costs of requisites relative to their resources and incomes. Thus the differences in capacities to absorb and develop technologies increase between the developed and the developing world. New developments for increasing health and wealth and for improving the quality of life are becoming knowledge-based. High rates of obsolescence, high rewards for application of new knowledge widely in a monopolistic-ownership route, ease of duplication of new technology, enhanced international commercial trade and keener competition, shift of support for scientific research from governments and international agencies to private-ownership enterprises requiring commercial returns on investments, and rising costs of energy and raw materials are forcing valuation of use of technology in commercial rather than social-benefit terms. The premium on new technology and its controlled use has become high. Consequently, openness is yielding place to restrictions. Much new knowledge and technology has relevance to national security and defence. Economic groupings of enterprises or countries also produce massive concentrations of resources and power for generation and use of technology for economic benefits.

It is in this context that there are increasing restrictions on and concerns regarding information and communication technology, new materials, energy, environment and ecology. Biotechnology is yet another area of great promise that offers scope for debates on opportunities and rights of sharing the benefits.

### International convention in biology

There are fundamental differences in perceptions of intellectual-property conventions related to biological sciences and technology from those related to the physical sciences. For instance, in the case of alleviation of human disease, it is not possible to patent techniques for surgery of all types—such as bypass heart surgery—, organs transplants, implant of heart valves, artificial limbs, dialysis for renal failure, plastic surgery, and surgical methods in cancer, appendicitis and neurosurgery. The actual use of

drugs, antibiotics or vaccines, or any form of diagnosis, prevention or cure of disease or malfunction are not patentable. Indeed, medical innovators are expected by convention to publicize information and train others to copy the techniques. Artificial insemination, *in vitro* fertilization and embryo transplants are such cases. Even cosmetic improvement by surgery or therapy is not patentable.

A similar convention prevails in animal husbandry, providing no patent cover for embryo transfer, artificial insemination, use of hormones and steroids in animal growth or milk production, animal vaccines, and drugs.

In the case of plants, tissue culture, plant breeding, cell culture and organ culture are in the public domain and considered prior art. Live plants, naturally occurring microorganisms, general methods of propagation, biological control of pests and weeds, and improvement of plant nutrition and output are not protected by patents. Hybrid lines are not generally patented but closely held by monopoly-secure control of parent plants. Even new techniques of genetic manipulation, by cell fusion, protoplast fusion, *Agrobacterium tumefaciens*, or shotgun firing of DNA, do not have patent protection.

New varieties developed by plant breeders in universities, agricultural research organizations supported by governments, and international agencies as well as philanthropic foundations at great effort and expense have been freely released and allowed to be propagated further nationally and internationally in the past. The green revolution in cereals and other major crops in the last three decades is the result of free exchange of information and plant varieties among scientists and countries.

Again, in the case of microorganisms obtained by selection for production of antibiotics, amino acids, enzymes, alcohol and industrial chemicals, or those for increasing biological nitrogen fixation, there are no patents. Commercial benefits are sought to be enforced by contracts in transfer of technology through restrictions on further transfer to third parties. Security and secrecy, rather than patents, have protected commercial returns. Such restrictions have been applied to closed factory-controlled operations, as in the case of fermentation, but not to those propagated in open-field conditions by large

numbers of small farmers. Breeders' rights on new seeds and plant varieties restrict further propagation, and these are relevant for plantations and large farms.

### Emerging trends

New trends are emerging in respect of rights and freedom in the use of techniques and materials related to biology or to improvement of health and productivity of life systems. While naturally occurring substances, including bioactives, cannot be patented, simple modifications or man-made combinations or the processes for production of these as well as natural materials could be patented. These include modified antibiotics, synthetic steroids, modified hormones and enzymes, anchored enzymes, organ-specific drug-delivery products by chemical combinations, drug formulations, heart valves, artificial teeth, plastic bags for blood storage, slow-release drug implants and micro-encapsulation products.

### Agriculture

In the case of agriculture, new varieties are sought to be protected by breeders' rights recognized in law in some countries, through which further propagation is restricted. Enforcement of such rights in the case of freely reproducible materials is only possible with large holdings of land, as in plantations or in very large farms. The breeder and supplier of primary seed or planting material and the farmer have common interests and benefits through practice of secrecy, security, and restriction on transfer. These are likely to be prevalent in high-value cash crops such as cashew, spices, essential-oil plants, medicinal plants and ornamental flowers. Even in these cases, infringements are difficult to prove. These cannot apply to freely propagated plants cultivated by small farmers as it is not possible to enforce rights economically.

There has been a small beginning in the USA towards providing patent recognition for genetically engineered life forms obtained by asexual methods within the same species or by introduction of genes from another species. Microorganisms such as *Escherichia coli*

in which human genes have been incorporated for production of human insulin, human growth hormone, human tissue-plasminogen activator and human streptokinase are examples. Microbial cells engineered to produce antigens and antibodies for use in vaccines against communicable diseases of man and animals are also considered new life forms qualifying for patents. In the case of plants such as tobacco, it has been possible to evolve plants incorporating microbial genes that provide resistance to plant virus disease. Disease-resistant elm trees and insect pest-resistant plants have also been produced by genetic engineering.

There are reservations and legal restrictions on the release of such genetically engineered varieties of plants and microorganisms for free, open cultivation on account of concerns of safety. However, it can be surmised that a very large number of disease-resistant plant varieties will become available in many countries through genetic engineering. In the absence of legal regulations or due to inability to enforce them, most of these will be propagated, as the techniques are relatively easy. Even though patent protection may be possible, they may not be enforceable in small-farm agriculture or in the case of major crops such as cereals, pulses, sugarcane, cotton and potato. In Asian agriculture, with small farms, such patent rights are not practicable. They may apply only to rubber, oilpalm, spices, tea, coffee, cocoa, and pulp and fibre related to the paper and rayon industries.

More genetically engineered organisms may emerge for pest and weed control, and there is a possibility of patent protection and effective implementation, at least for a short period. Secrecy and control over availability of these may provide more returns than patents. Similar conditions may apply to extracts for photosynthesis activation. In many instances, trade marks and brand names of products such as seeds, plant-growth promoters, photosynthesis activators, natural biological-nitrogen-fixing organisms, and plantlets for propagation could ensure commercial success by virtue of providing assurance of quality, and associated advisory and input services for soil testing and fertilizer and pesticide application. Patents themselves may be less relevant in commercial terms in such cases.

### *Animal husbandry and fisheries*

There are as yet no patent rights for cross-bred high-growth, high-milk-yielding or high-wool-producing animals as these arise from natural breeding. But transgenic animals may emerge that qualify for patent protection. However, there is considerable reservation on the wisdom of transgenesis in animal systems, and, in the foreseeable future, there are no real large-scale possibilities.

Patents will, however, be available for a variety of new products for animal health, growth and productivity. These include disease-diagnostic devices, growth promoters, milk-yield enhancers, fur- and wool-production promoters and fertility regulators. There may be new technologies for improving digestibility and nutritional quality of feeds. Techniques for fractionation of sperm to provide concentrations that would substantially favour a specifically desired sex in offspring may emerge. This would enable, for instance, the directed production of female buffalo or cows for dairying, avoiding birth of male calves. Such selection may be favoured in countries that do not have a need for draught animals or bovine meat. Such techniques may be patentable. There will be opportunities for production of desired amino acids and their incorporation in poultry, pig and fish feeds. Inhibition of methanogenesis and wastage of feed by methane production and evacuation by cattle through chemicals and biochemicals could enhance feed-growth efficiency in ruminants. There are possibilities of increasing milk-yield period without pregnancy and calving by manipulation with hormones that would induce or prolong lactation. These products and techniques would also qualify for patents. Already, alteration of sex ratio in fish by use of hormones has been demonstrated. In the virtual absence of males, growth rates are markedly high. Hormones may also play a part in rapid growth in shellfish and high-value fish such as trout in fish farms. Opportunities for biotechnology are very high indeed.

### **New principles and concepts**

While the conventions of openness and non-patentability of innovations in biology are being modified in the case of genetically engineered life forms and

new breeders' rights are growing for traditional plant breeding, there are likely to be many reservations on providing such rights, especially considering the needs of developing countries. On the other hand, the impracticability of enforcing such rights in small farms in such countries may lead to refusal to transfer the advances. There may be international pressures for providing patent protection for many advances in biotechnology and genetic engineering, even though these may favour only a small number of companies in developed countries. It is therefore appropriate to consider the principles of patent rights in biology and also to evolve methods for ensuring returns to innovators while obtaining flow of advances for wide benefits in the developing world. Some new concepts and principles are outlined below.

Biological diversity is the property of the whole world and of all mankind. The total genes of all organisms are the inheritance of all mankind. Therefore, all organisms and life forms that have arisen to date by evolution and natural mutation and selection are regarded as nature and as not patentable. When, through genetic engineering, a modified organism is created, it has been proposed that it should be regarded as an invention and hence patentable. In this process, a particular genetic property and its specific expression through production of specific chemical entities known in one organism are transferred to another organism. This could be considered a relocation of a naturally occurring gene in a new environment. It could also be likened to assembly or arrangement of semiconductors with new properties of storage of information and ability of control. Such arrangements and assemblies are themselves not accepted at present in most countries as original inventions that merit patent protection. It is therefore not unreasonable to regard all genetically engineered organisms, including transgenic ones, as natural products and not as entirely new and original products or inventions. It is thus possible to argue very forcibly that genetically engineered organisms are not patentable. There is increasing evidence that genetic transfer occurs in nature, and this adds strength to the agreements favouring non-patentability of man-made, genetically engineered organisms.

New methods and techniques of genetic engineering may be devised, and such processes could be termed inventions. Patents on such techniques would prevent their wide use and application, to the disadvantage of the world community. It is therefore suggested that steps be taken, by international consultation and agreement, to disallow patent protection for such techniques. Scientific academies and international agencies should evolve such a principle and insist that all such techniques be disclosed, as in the past, in scientific journals first and become property in the public domain.

It would also be appropriate for all agencies providing grants and support for research in modern biology and developmental biology to stipulate that techniques of manipulation of genes be freely published. Any use of such methods for commercial purposes would then be regarded as prior art and not patentable. Large-scale use of genetic-engineering techniques is already covered in many countries by stipulation, guidelines or laws requiring prior approval of expert committees for safety review. Such reviews are carried out at public expenditure and would not be possible without the very large expenditure on basic research, discussions by academies, and publications. It is therefore entirely reasonable to regard any specific innovation by an individual or company made as a corollary or derivative of basic research or after approval for large-scale use for commercial purposes as not qualifying for protection by patent. This would eliminate monopoly over new techniques for commercial gains. Even if any rights are to be granted, such patent rights could be the property of national academies or international agencies.

### **Actions required for international agreements**

It has been proposed above that genetically engineered organisms and new techniques of genetic engineering

should not qualify for patent protection. It is, however, recognized that these concepts are counter to the beliefs of many scientists and industrial commercial companies. Therefore substantial debate and discussions are necessary to evolve guidelines and principles and to obtain international agreements that would ensure rapid progress and wide application for the benefit of all mankind. There should also be adequate incentives for such research and evolution of technologies. Some actions for attaining these objectives are suggested below.

- (i) Biotechnology and genetic-engineering advances that have a major potential for increasing agricultural production and animal productivity will contribute to reduction of hunger, malnutrition, ill health and disease, and such advances of large benefit to mankind should be regarded as similar to new techniques in surgery or therapy. All attempts should be made to make them available freely without the restrictions of patent rights. Professional scientists, technologists and engineers should evolve codes of conduct similar to those in medical practice and surgery.
- (ii) These concepts should be drafted as documents for circulation to national scientific academies and societies for comments and debate.
- (iii) Governments and research funding agencies should increase publicly funded support for basic studies and for application of results in agriculture and animal husbandry. Opportunities should be created for free exchange of information, genetic sources, new varieties and organisms as in the past. Training, particularly for those from developing countries, should be increased.
- (iv) Academies and governments should provide high-level public recognition of contributions by scientist groups and companies in biotechnology applications through awards.
- (v) Funding by international agencies for cooperative research, and technology evaluation, transfer and widespread

use should be substantially increased. Investments in efficient and increased food production using biotechnology in all countries is preferable to constant aid and donation of food in conditions of famine.

(vi) Companies evolving new technologies of value should be encouraged in their efforts by grants and support to the extent necessary. The rights of use of technology, at least after a short initial period, should be purchased by international agencies, with due compensation to the companies, and then made available widely against modest payments, taking note of overall benefit and capacity to pay.

(vii) Substantial efforts should be made by a body of international experts promoted preferably by UN organizations to familiarize leaders in government and apex elected-representative organizations such as national parliaments in developing countries regarding the potentials, limitations and safety aspects of biotechnology and genetic engineering, and systems for the wide application of advances, with particular emphasis on agriculture and animal productivity. Technologies have to be modified to meet national and regional needs in developing countries.

(viii) Special coordinated research efforts should be promoted and supported for evolving varieties of primary crops with drought and pest resistance in tropical conditions, taking note of local climate, natural resources and types of pests, and using techniques of biotechnology. Similar action is required for development of animal breeds, animal vaccines and fodder in developing countries. Critical viable groups of expertise with facilities should be available nationally and in regions for meeting these objectives. Biotechnology applications for post-harvest preservation and processing and in fisheries should also be promoted similarly.

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