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Recent developments in biotechnology: An Indian perspective

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Summary — The basic concept of the term, biotechnology, is defined. Global as well as Indian developments in the field of biotechnology are traced. The question of patenting biotechnological inventions is discussed in the context of Indian Patents Act 1970. It is concluded that Indian Patents Act is broad enough to cover the claims of biotechnology industry and there is no need to modify and amend it under the international pressure being brought on India at present through various fora.

Biotechnology, as a term although used first in 1920s, has been existing as an activity since the dawn of civilization. Broadly defined, it is the application of scientific and engineering principles to the processing of materials by biological agents (such as plants or animal or microorganism, or parts thereof) to produce goods and services. Its classical usage since ages has been in baking, brewing, cheese-making, improving agriculture, animal husbandry, etc. Likewise, genetic modification of living things by 'selection' or 'mating' or 'cross-breeding' has been practised since long as crude genetic manipulation techniques. However, it is the use of novel biological techniques, such as recombinant DNA, cell fusion, monoclonal antibody and bioprocessing, with an ability to select and manipulate genetic material which has revolutionized this area into what is known as modern biotechnology.

Biotechnology—The Commercial Cornucopia

The World Scene

The economic or commercial implications of the use of these new techniques are enormous as biotechnology itself is not an industry defined by products or services; it is basically a means of production. The range of its applications is very wide, extending from food to fuel, from waste disposal to pharmaceuticals. It is widely believed that it is the advancement in biotechnology alone which will spur the next industrial revolution. George P. Smith[1] says, *interalia*, "the biotechnology revolution is not only developing new sources of power to alter creatures, including humans, but promoting new processes that enable manufacture of all the materials that nature has used throughout those billions of years that the Earth has been in existence. Ultimately, the power will even be found to design and produce new materials that natural selection never managed to invent". It is not a utopia. Biotechnology has already ushered in technologies which (i) allow introduction of desired characters in life forms, (ii) are highly energy-efficient thus cost-effective, (iii) decrease to an appreciable extent the levels and character of industrial operations.

The impact of the use of modern biotechnology techniques on commercial operations has not been fully documented world-wide; some estimates are, however, available for USA which say that for an estimated R&D investment of about US $ 2 billion, the turnover by the year 2000 is expected to touch US $ 50 billion from the current level of US $ 4 billion. For India no estimates of the turnover of modern biotechnology-based industries are available, but the R&D expenditure, mainly in government sector, however, is estimated to be between US $ 25-30 million per year. A recent report[2] on "World Healthcare Biotechnology Industry" estimates the current world market for healthcare products between US $ 6 and 8 billion.

Such a promising outlook on the potential applications of biotechnology-based techniques in healthcare product area has spawned hundreds of biotechnology companies world over which meet not only the healthcare needs of the developed countries but also are likely to bring in products relevant to the needs of the developing world, i.e. for health, food, malnutrition, energy, etc. Already there are several healthcare products made by rDNA technology, such as interleukin-1 for cancer chemotherapy; growth factors for immunodeficiency states, resistant infections, wound healing; vaccines for hepatitis, herpes and malaria prophylaxis; hormones such as somatropin hGH and

humatrope hGH for deficiency; protein C, a blood product, for blood factor deficiency and several more products including monoclonal antibodies produced by non-recombinant gene technology which are at various stages of commercialization and have a huge commercial potential worldwide. With such heavy financial stakes, the inventors look towards patents to promote inventiveness, protect commercial interests and grant them the rights to the intellectual property generated, which, in its wake, has brought in pressure through various bilateral and multilateral fora, over several developing countries including India, to extend intellectual property rights and protection to biotechnology-based products and processes in line with the international laws/treaties.

The Indian Scene

The Indian scene is also somewhat promising as biotechnology and genetic engineering, as an approach, have got a sharp focus with the establishment of a separate Government department to initiate, coordinate and monitor activities in this area. This has resulted in several biotechnology-based products or processes, such as

(a) birth of buffalo calves using embryo transfer technology,
(b) production of diagnostic kits for filaria, early pregnancy, typhoid fever and amoebic liver abscess,
(c) DNA finger printing for identification of individuals,
(d) plant tissue culture propagation of bamboo, cardamom and coconut,
(e) field trials of some male and female birth-control vaccines and a few whole organism-based leprosy vaccines,
(f) prawn aquaculture, and
(g) initiation of several vaccine production programmes to control communicable diseases of children through vaccination.

These products and processes are expected to have commercial potential as they would contribute significantly in increasing agriculture production, animal productivity and to the reduction in hunger, malnutrition, ill health and disease. In addition to these tangible gains, several R&D programmes, such as rDNA-based production of biomolecules, e.g. insulin, growth hormones, hCG, FSH, interleukins; production of some specific monoclonal and polyclonal antibodies; development of immunodiagnostics and DNA probes for communicable diseases; and production of synthetic peptides, oligonucleotides, have been initiated, which have an immense value.

However, the sheer size of the potential economic returns on products, processes and services based upon the use of living forms is bringing in pressures upon the Indian Government from various vested interests, both at national and international levels, to extend the scope of patent protection to modern biotechnology-based products and also to change its present patent regime in favour of (a) introduction of all encompassing product patents, even for products required for healthcare; (b) uniform period of patent protection of 20 years; (c) no compulsory licensing and no licence of right, and (d) reversal of burden of proof. Keeping in view the compulsion of international diplomacy as well as weighing it against our national commitments and needs, the point to ponder here is whether India should create specific patent rules and regulations for such products and also bring in changes as suggested, or the existing Patents Act is sufficient to take care of newer developments in these areas. This article seeks to examine these questions.

Patent System in India

The Indian Patent system comprising statutes and acts governing the subject of Intellectual Property Rights and their protection particularly the patents rights is about 140 years old. Established as Patents Act No. VI of 1856, it was basically structured on the lines of British Patent Act of 1852 and provided for a monopoly right to an inventor for 14 years as well as granted him the "right of importation". This system generally protected the interests of British companies and continued to be practised with minor modification till Independence.

The period immediately after Independence, however, saw the Patents and Design Amendment Bill of 1950 and the Patent Bill 1950. Both these made some superficial changes in the Act thereby leaving the basic structure largely unaltered. It was Justice Ayyangar Committee which put forth, in 1959, a comprehensive report which formed the basis of new Indian Patents Act 1970, adopted and enforced from 1972.

This new Patents Act 1970, which describes a patent as the exclusive right to use or exercise an invention granted to a person for a limited period in consideration of the disclosure of the invention, has several salient features:

Table 1—Biotechnological inventions: Status of protection in some countries

Country	Method of treatment of human/ animal	Method of agriculture or horticulture	Micro-organisms	Substances obtained through microbio-logical processes	Plant varieties	Animal varieties	Essentially biological processes for production of plant or animal varieties
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
India	No	No	No	No	No	No	No
China	No	Yes	Yes	Yes	No	No	Yes
EPC	No	Yes	Yes	Yes	No	No	No
Japan	No	Yes	Yes	Yes	Yes	Yes*	Yes
CIS (Formerly USSR)	No	Yes	Yes	Yes	No	No	Yes
USA	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Australia**	-	-	Yes	Yes	Yes	Yes	Yes
Mexico	-	-	No	No	No	No	No
Canada	No	No	No	Yes	No	-	Yes
Chile	-	***	-	-	-	-	-
Brazil	-	-	No	No	No	No	No
Hungary	-	-	-	Yes	Yes	Yes	Yes

* Have recently notified so

** In the process of being adopted

*** Only trademark protection on seed varieties

(i) Product patent for all inventions, except for those substances to be used as food, medicines or drugs or substances produced by chemical processes for which only process patent;

(ii) All patents to have a 14 years term, except for substances to be used as food, medicines or drugs for which a term of 7 years from the date of application or 5 years from the date of sealing of patent, whichever is earlier;

(iii) at par treatment for patentees of all nationalities;

(iv) provisions of compulsory licensing; and

(v) licences of right.

These provisions have enabled our national sector industry, especially pharmaceutical industry to meet our country's requirements of drugs and pharmaceuticals at much competitive rates. The industry could establish a self-reliant technology- base whereby it could synthesize most of bulk drugs required to meet formulation needs of the country. The industry is now mature enough to absorb all technological innovations and produce the desired drugs, chemicals or intermediates through the most cost- effective route by it the traditional synthetic or the use of biotechnological techniques.

Indian Patent System: Requirements in Biotechnology Patenting

The Indian Patent laws are clear on the distinction between patentable and non-patentable subject matters as they apply to living matter. The non-patentable categories, *interalia*,

(i) "a method of agriculture or horticulture",

(ii) "any process for medical, surgical, curative, prophylactic or other treatment, etc. of human beings or any process for a similar treatment of animals or plants to render them free of diseases or to increase their economic value or that of their product", have, however, become a subject of much interest and debate as the use of biotechnological techniques, such as recombinant DNA, cell fusion, monoclonal antibody technology and new bioprocesses for commercial production, is widespread now. Further, such a use has created inventions which are

themselves alive; so to have intellectual property rights on them would mean:

(i) Patenting of microorganisms and cells *per se* or such products made from them which do not have any living matter,

(ii) patenting of plants and plant varieties *per se* or mutated/genetically improved strains of them, and

(iii) patenting of human engineered animals.

Most of the patents, which could be filed in these areas in near future, may be beyond the realm of our well-resolved laws of patenting. The patents on inanimate subjects do not confront one with such issues—scientific, regulatory, political, and ethical which the use of newer techniques in biotechnology has thrown open.

Indian laws on the patenting of replicating organisms *per se* or on the products derived from them are uncertain but so are the laws of many other countries as well as international treaties (Table 1). Similarly, the question about the scope of patent protection and the question whether naturally occurring substances, microorganisms or other biological materials may be considered as novel when found freely occurring in nature are not yet resolved. Likewise, what constitutes inventive step for the purpose of patenting and also the industrial applicability of the invention are two important requirements for patenting in modern biotechnology pending to be sorted out.

Patenting of Products of Classical Biotechnology

In applying the provisions as contained in Indian Patents Act 1970 to biotechnology inventions some of the considerations which emerge are:

(i) Whether the existing Patents Act needs revision and a separate provision is needed for biotechnology innovations or patenting requirements be met by existing provisions.

(ii) The patentability of microorganisms *per se*, both naturally occurring and man-made.

(iii) Question of novelty considered in light of 'discovery' vs 'invention' as applied to microorganism.

(iv) Disclosure of living entities for subsequent commercial utilization.

(v) Reconsideration of providing patent protection to processes or methods of treatment of human beings, plants and animals.

These questions, though very pertinent, seem to be a little premature for us. Although India has not formulated any specific guideline so far for the grant of patents on inventions involving use of techniques of modern biotechnology and it is not a member of any international convention either, the patenting activity in this area is being carried out since long. The structure of Indian Patents Act and the provisions contained therein are basically sound and adequate for inventions in classical biotechnology. So far in India it is predominantly the classical biotechnology techniques which are being used in industrial operations although a few small units have come up which use newer genetic bioprocessing and breeding techniques.

The patenting activity has stayed restricted to sectors like pharmaceuticals, chemicals, agriculture, etc. A report entitled "Indian Patent in Biotechnology published during 1972-88" brought out by the Department of Biotechnology[3] mentions that patenting activity in biotechnology in India is basically limited to pharmaceutical sector primarily for processes for preparation of antibiotics, enzymes, vitamins, antibodies and vaccines. In addition there have been inventions relating to production of alcohol, polysaccharides, biocides, plant cell and tissue culture, baker's yeast, food additives, biogas, and processes for waste water and affluent treatment, etc. This report further says that out of nearly 950 classical biotechnology-related patents, nearly 75 per cent of them originated from foreign countries mainly from US and European companies. Most of these patents are covered under *Human Necessities* and *Chemistry and Metallurgy* sections of International Patent Classification.

Indian Patent Act—A Need to Maintain *Status Quo*

Indian Patent laws are sufficiently broad-based as to examine the claims of most of inventions relating to classical biotechnology. A separate patent law or even amending some of the provisions as contained in Section 3 of the Act at this juncture is unwarranted. India must build its own capabilities in the area of modern biotechnology before any serious consideration is given to amending the existing Act. A study[4] reported by scientists from Central Drug Research Institute, Lucknow, has categorically concluded, after looking into the patents filed in the area of biotechnology, that most of the patents have come from foreign MNC's and Indian patents are far and too few. According to them there is no sufficient empirical data to warrant modification of the present Indian Patents Act.

The data presented in Table 1 show that rules for patenting of living matter are widely varying in most of the countries. If all these countries can differ and wait, India too can wait and watch. The demand and the pressure being exerted by some industrial countries through bilateral or multilateral fora on India to change

its present patent regime should be resisted. The changes brought about by Indian Patents Act 1970 have helped the Indian industry grow, and it is not difficult to imagine the setback to public health and other societal needs if we go back on these.

Concluding Remarks

Biotechnology has come to stay and eventually to surpass all other industrial sectors. It is the future on which hinges the improvements in health, food, and environment. Its commercial and technological capabilities have enormous potential with inventions being reported at a rapid pace. The Intellectual Property protection is germane to any invention which leads to innovative commercial technologies. India which has so far not addressed or applied its patent laws to modern biotechnological inventions may have to do so later. Till that time, which may take 5-10 years for these novel technologies to fructify into useful processes or products our Patents Act is sufficient.

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