3. The provisions in relation to compulsory license shall, subject to necessary modifications, apply to 'exclusive marketing rights' as well.
4. In the interest of security of India, the government of India may not disclose any information relating to any patentable invention, and take action including the revocation of any patent, provided that the intention for the same is notified in the official gazette before taking any action.

41.6. PROTECTION OF BIOTECHNOLOGICAL INVENTIONS

Biotechnological inventions are concerned with life forms and involve one or more of the following : (*i*) various methods/processes of generating useful biotechnological products, (*ii*) Various biotechnological products, *e.g.*, antibiotics, purified vitamins etc., (*iii*) Applications of the various processes/products, *e.g.*, application of a biocontrol agent to manage a pest, etc., (*iv*) various microorganisms, cell lines, plant/animal lines obtained through biotechnological approaches. (*v*) various DNA sequences and the proteins encoded, if any, by them, and (*vi*) biotechnological processes/technologies for modification of the properties of various organisms.

The various **production processes** and the **products** obtained from them are ordinarily protected by patents, and so are the **applications of these products**. However, international conventions do not permit patenting of processes or product applications concerning alleviation of human diseases. For example, techniques of surgery are not patentable. Similarly, the use of a product for treatment, diagnosis or prevention of disease can not be patented.

The European Patent Office (EPO) has suggested that isolation of a substance from nature is merely a 'discovery' and, therefore, should not be patentable. However, the process developed for the isolation of this product is patentable. But if the substance is characterized and is found to be 'new' having 'no previously recognized' existence, the substance *per se* should be patentable. In U.S.A., the U.S. Patents and Trademark office (USPTO) held that natural products were not patentable. But in 1977, the US Court of Customs and Appeals clarified that, although a natural product *per se* is not patentable, a *new* 'form' or 'composition' of the product can be patented. This decision has provided the basis for patenting of purified natural products considering them as 'new forms' or 'composition' of the product. The ***processes used for genetic modification*** of various organisms are patentable virtually in all countries, including India.

41.6.1. Patenting of Genes and DNA Sequences

An artificially synthesized gene is considered patentable in almost all developed countries. The patenting of genes isolated from naturally occurring organisms, however, is rather controversial. Patents are now allowed on such genes in USA; the first patent was awarded for the gene *aroA* isolated from a mutant bacterial strain and intended for transfer into plants to confer glyphosate resistance. The patent for *aroA* is held by Calgene, Inc., USA in terms of a DNA sequence containing this gene. The US patent statute (35 USC 101) requires an invention to be 'useful' for being patented. The term 'useful' has been interpreted

to mean 'practical utility'. Many genes/DNA sequences may not have any known practical utility at the time of their isolation and, as a result, would not be patentable. But this requirement was relaxed and patent awarded for isolated genes, vectors and transformed cells expressing the hormone angiogenesis factor (AGF), which increases vascularization. When the patent application for AGP was filed in 1985, there was no known practical utility for AGF. Thus U.S.A., as in other cases, is making radical changes in its attitude towards patenting of genes and DNA sequences.

In contrast, courts in UK held that natural genes are not patentable. One may imagine that U.S.A. and similar-minded countries will build up pressure on other countries to allow patents for genes isolated from natural organisms. The protein encoded by the gene would be covered under the patent if it were considered novel. The use of such genes to produce transgenic organisms, and such organisms themselves, will also be protected by the patent, provided they exhibit novel desirable attributes.

In 1998, the European parliament, has approved provisions for patenting of DNA sequences where a use or technological process is specified. Further, new plant varieties incorporating a technological process will be patentable. This EU directive is now to be incorporated into the national laws of the member states.

41.6.2. Gene Patents and Genetic Resources

The developing countries are technology poor, but gene rich. In contrast, developed countries are technology rich but gene poor. For example, not a single crop of significance grown in U.S.A. had originated there. Coupled with this, developing countries are also characterised by limited financial capabilities, usually weak infrastructure and a misplaced sense of social and ethical values. In contrast, developed countries are strong financially, well-equipped infrastructurally and, in general, have a society responsive to challenges of a changing world agricultural/technological scenario.

The developed countries have made extensive collections of germplasm of all important crops, conserved and characterised them and are now deploying them for the development of new improved cultivars. Alas, few developing countries have made adequate efforts to collect, conserve and characterise the germplasms of their own crops, let alone to speak of collections from elsewhere. A time may soon come when many developing countries may virtually depend for their germplasm supply on the developed countries, the price tag of which is likely to match the need. This in itself is a disastrous possibility and should be avoided by every nation. However, the moral issues (*e.g.*, germplasm is a common heritage of humanity, etc.) concerning such a situation are another story, but often money speaks louder than morals.

Another aspect of germplasm collections made from the developing nations relates to the patenting of useful genes isolated from them by the organizations/individuals of developed countries. The use for genetic transformation of such a gene by anyone may be prohibited or, at the least, would carry a suitable fee. Thus it is ironical that the country/countries, which was/were the source of a gene may not be allowed/may be charged a fee for the use of the same gene.

The story of rice gene *Xa21*, which specifies resistance to bacterial leaf blight (caused by *Xanthomonas oryzae*), would illustrate this point. This gene was originally discovered by R.C. Chaudhary working in Patna (Bihar) in the wild species *Oryza longistaminata*, a native of Male. Subsequently, Dr. G.S. Khush working at IRRI, Philippines transferred it into *O. sativa*, named it as *Xa21* and located it on chromosome 11. This material was passed on to Dr. Tanksley (U.S.A.) who identified the molecular markers flanking *Xa41*. Ultimately, *Xa21* was isolated at University of California, Davis (U.S.A.) and patented. The use of *Xa21*, therefore, is now controlled by its patent holder, although *O. longistaminata*, from which this gene was isolated, was collected from Male, Africa.

41.6.3. Patenting of Life Forms

Life forms, *e.g.*, microorganisms, plants and animals, are not patentable in India under the provisions of Indian Patent Act (1970). However, patents can be obtained for various biotechnological processes and product applications within the limitation of international conventions.

In U.S.A., European Union and other developed countries, microorganisms isolated from nature or obtained by simple mutagenesis and/or selection from natural isolates are not considered patentable. But microorganisms modified by using more ingenious techniques, *e.g.*, genetic engineering, are now patentable. The first patent to a microorganism was allowed by the American Supreme Court in 1980. Soon after, in 1981, a patent was allowed in European Union for a microorganism by EPO.

Among the higher organisms, plants were the first to be patented in U.S.A.; in 1985, a maize line overproducing tryptophan was allowed a patent. Patenting of plant lines is now a common practice in USA. In addition to patent protection, plant materials can also be protected under a system of PBR. The member countries of the European Patent Organization (Belgium, Denmark, France, Germany, Greece, Ireland, Italy, Luxembourg, the Netherlands, Portugal, Spain, and the U.K. of the European Union), and Austria, Liechtenstein, Monaco, Sweden and Switzerland follow the Article 53 of the European Patent Convention (EPC). ***Article 53(a)*** excludes such inventions that are contrary to the public order of morality from patent protection. ***Article 53(b)*** excludes from patent protection (1) plant and animal varieties, and (2) essential biological processes for the production of plants and animals. Despite the provisions of *Article 53(b)* of EPC, the first patent on a plant was awarded in 1989 by EPO. In this case, the plant in question was not considered to be a ***variety***, which was defined by the Technical Board of Appeal of the EPO as 'a multiplicity of plants, which are largely homogeneous in their characteristics that remain stable after every propagation.'

The biotechnology companies in Europe strongly favour the patenting of inventions based on living materials at par with that in U.S.A. and Japan. The European Commission proposed in 1988 a *Council Directive on the Legal Protection of Biotechnological Inventions*. This directive seeks patent protection for biological materials, including plants and animals, microbiological processes, and subsequent generations derived from patented biological materials. However, plant and animal varieties, as well as essential biological processes, are to be excluded from patent protection. The European Parliament favours the inclusion of farmer's privilege in the directive; this provision will allow farmers to resow the seeds

produced from a patented material on their farm and to rear progeny of patented livestock to renew their stock on their own farm.

Animal materials are protected by patents. U.S.A. again was the trendsetter in this regard; the first animal patent in the world was awarded in U.S.A. in 1988 to 'oncomouse'. Subsequently, other animal patents have been allowed in U.S.A., *e.g.*, of a polyploid oyster produced by applying hydrostatic pressure to zygotes. In U.S.A., '*non-naturally occurring non-human multicellular organisms*' are now considered patentable by the US Patent and Trademark Office.

In 1992, EPO also awarded a patent for 'oncomouse'. The EPO did not consider oncomouse as an animal variety; as a result, it was exempted from the application of Article 53(b) of EPC. It was also ruled that Article 53(a) of EPC was not applicable in this case as the benefits to mankind out-weigh the suffering of mice. Obviously, the meaning and the scope of term 'variety' needs to be clarified and streamlined.

41.6.4. Should Life Forms Be Patented ?

'Can life forms be patented ?' is no more a valid question as they are being patented in U.S.A., European Union and Japan. The arguments for award of such patents are various, but the major considerations underlying them all are simply the monetary benefits and the associated impetus to biotechnological inventions resulting from them. It is argued with reasonable justification that an effective protection of biotechnological inventions, including life forms, will encourage multinational corporations (MNCs) to invest in research efforts in this area. This, in turn, would lead to newer and more and more useful innovations in increasingly newer fields. These will ultimately result in increasingly greater economic benefits to all concerned, including the society at large, which will have an access to more useful and often cheaper products and services generated through biotechnology.

It may be safely stated that the primary motivation in commercial activities is profit. The opportunities of deriving profits from inventions depend, if other factors were comparable, on the extent and degree of protection awarded to their IPR by a nation. Therefore, MNCs and other commercial houses will selectively invest in research and development (R&D) efforts in those areas where greater and more effective protection is available. Thus in the issue of IPR protection, inventors (MNCs and others) constitute one party : their chief concern is the maximization of the economic returns on their inventions.

The society, however, does not confine its concerns to only economic aspects; it is also alive to moral, ethical, environmental, social and political issues. In addition, a society is rarely a homogeneous mass; it consists of a variety of interest groups, each emphasising a separate issue. The various objections raised against patenting of life forms are largely ethical and political in nature. Many non-government organizations (NGOs) have filed legal objections to the issuance of patent on the oncomouse in Europe. In U.S.A., USPTO has awarded patents on plants and animals, as an administrative decision; the legal validity of these patents is not yet clear as the US Supreme Court is yet to pronounce its judgement on patenting of life forms other than microorganisms.

Thus society becomes the second party in the issue of IPR protection. In general, one or the other segment of the society will like to exclude some or the other subject from patent