CHAPTER 41

INTELLECTUAL PROPERTY RIGHTS

41.1. INTRODUCTION

The adage 'necessity is the mother of invention" underlines the basic fact that all human endeavour, especially in the worldly domain, is directed at fulfilling some human need. The returns from almost all human endeavours can ultimately be translated into monetary gains. Thus, *monetary profit is the single most important, in most cases the only, motive behind man's relentless toil, inventiveness and ingenuity.* Quite often, the motive of profit may be shrouded in the garb of charity from both individuals and, more so, of foundations and other organizations.

Societies and governments have long recognized this basic fact and have devised various ways to reward their inventors so that they were encouraged to work with greater zeal and devotion to develop newer more useful inventions. The earliest record of such a measure dates back to 7th century BC. in the Greek colony of Saberis, south of Italy; the discoverer of a food recipe was given the exclusive right to use this recipe for one year. The first law on patent was passed in Venice in 1474, which gave monopoly rights to artisans for their inventions. In 1623, the House of commons of U.K. passed the Act of Properietariship.

In an ideal situation, an inventor should get a reward that is proportionate to the benefit accruing to the society from his invention. The inventor and society will ordinarily stand

opposite each other on the questions of the proportion that should go the inventor and the quantum of the benefit accruing or likely to accure from the invention. In any case, the inventor and the society need each other and should, in the best interest of themselves, be appreciative of each other's positions and aspirations.

41.2. HISTORY OF INTELLECTUAL PROPERTY RIGHTS IN INDIA

In India, innovations and novel techniques were retained within the families/small social groups that developed them, and there was no other system of protecting their rights to the knowledge so generated. In 1856, the then Government of India introduced the ***Act of Protection of Inventions***; this act was based on the British Patent Law of 1852. Later, ***Patents and Designs Protection Act*** was passed in 1872. In 1883, the ***Protection of Inventions Act*** was introduced; it was consolidated as ***Inventions and Designs Act*** in 1888. On August 15, 1947, the Indian patents and designs came under the management of Controller of Patents and Designs.

The currently operative patents act, the ***Indian Patents Act (1970),*** was introduced in the parliament in 1965, was modified in 1967 and was passed in 1970. Protection of designs is covered by the ***Indian Patent and Design Act (1911)*** with amendments in 1978 and amended rules in 1985. Trademark protection is in force since June 1, 1948 under the 1940 Act; this Act was amended as ***Indian Trade and Merchandise Marks Act (1958),*** which came in force on November 25, 1959. The ***copyright laws*** in India ***[The Indian Copyright Act (1957), ammended in 1999]*** are as per international standards.

41.3. INTELLECTUAL PROPERTY

The dictionary meaning of ***property*** is 'estate whether in lands, goods or money'; such property is often referred to as ***tangible***, ***material*** or ***physical property***. The ownership of and the associated rights to physical property are protected by the laws of the land. In contrast, ***intellectual property*** is an idea, a design, an invention, a manuscript, etc., which can ultimately give rise to a useful product/application. The development of such a property, as a rule, requires intellectual inputs, ingenuity and innovativeness; it also demands considerable monetary and other resources. Therefore, the inventor of an intellectual property would like to ensure at least a fair reward for his invention. *But the major problem with intellectual properties is that they can be copied, imitated or reproduced;* this minimises the returns to the original inventor. The foregoing discussion recognizes the right of an inventor to derive economic benefits from his invention (*i.e.*, intellectual property); this right is called ***intellectual property right*** (IPR). *The IPR, however, is recognized by the governments only so long as it is not to the detriment of the society.*

41.4. PROTECTION OF INTELLECTUAL PROPERTY RIGHTS

The protection of IPR may take several forms depending mainly on the type of intellectual property and the type of protection sought; each form of protection has its own advantages

and pitfalls. The main forms of IPR protection are as follows: (1) trade secrets, (2) patents, (3) plant breeder's rights (PBR) and (4) copyright.

41.4.1. Trade Secret

When the individual/organization owning an intellectual property does not disclose the property to any one and keeps it as a closely guarded secret to promote his business interests, it is called ***trade secret***. Trade secret may relate to formulae, processes or materials. The best guarded secret of the modern times concerns the formulation of Coca Cola. In the area of biotechnology, materials kept as trade secret include, cell lines, microorganism strains, production processes, etc. Trade secrets offer the following advantages. (1) They are for unlimited duration. (2) It is not necessary to satisfy the rather stringent requirements for protection under, say, patents. (3) The costs of filing, contesting and enforcing patents is saved. (4) The risk of someone improving upon the product, process, etc. is minimised.

Trade secrets, however, suffer from the following drawbacks, which often outweigh their advantages. (1) Maintaining a trade secret itself is a costly affair. (2) It offers no protection from independent innovation/invention. (3) Nondisclosure of the invention/innovation does not give others a chance to improve upon the original invention. This prevents, or at least delays, progress in the area of a trade secret, and society/nation/humanity is the loser in such cases. (4) It cannot be applied to many inventions, *e.g.*, equipment designs, plant varieties, books, etc.

41.4.2. Patent

A ***patent*** is the right granted by a government to an inventor to exclude others from imitating, manufacturing, using or selling the invention in question for commercial use during the specified period. Patents are granted for (1) an invention (including a product), (2) innovation/improvement in an invention, (3) the process/product of an invention and (4) a concept.

41.4.2.1. *Patent Requirements*. The chief requirements for the grant of a patent are as follows: (*i*) novelty, (*ii*) inventiveness, (*iii*) industrial application and usefulness, (*iv*) patentability, and (*v*) disclosure.

1. **Novelty**. The invention must be new and should not be already known to the public.

2. **Inventiveness.** The invention should not be obvious to a person skilled in the art, and should represent an innovation.

3. **Industrial Application and Usefulness.** The subject matter of the patent must have an industrial application, either immediate or in the future, and this application should be useful to the society/nation.

4. **Patentability.** The subject matter of the patent must be patentable under the existing law and its current interpretation. This criterion, at present, varies from country to country and with time within the same country. Two examples should clarify the situation. *The Indian*

Patent Act of 1970 did not allow product patents in pharmaceuticals, foods and agrochemicals. But this Act has now been ammended as Indian Patents (ammendment) Act (1999); the new Act allows product patents, except for some specified medicines/drugs.

The concept of patentable subject matter is bound to change with time. The Patent and Trademark Office (PTO) of U.S.A. regarded natural products and organisms as 'products of nature'; as a result, organisms and natural products as such were not patentable in U.S.A. In 1977, it was clarified by the U.S. Court of Customs and Appeals that a natural product *per se* could not be patented, but *a patent could be claimed for any new form* or *composition*. This interpretation permitted the patenting of purified natural compounds like azadirachtin (purified from *neem, Azadirachta indica*). Subsequently in 1980, the American Supreme Court ruled that a live, human-made (genetically-engineered) microorganism can be patented under the American patent law as a "manufacture" or "composition of matter" (Diamond *vs* Chakraborty case). In this patent, the subject of claim by A.M. Chakraborty was a new strain of *Pseudomonas*, derived from natural isolates by genetic manipulation, and capable of treating oil spills. Subsequently, patentability was extended to plants as well as animals (Section 20.6.3).

A patent entitled 'Basmati Rice Line and Grain' for a novel, high yielding, medium dwarf, photoinsensitive rice having all the desirable features of basmati rice was awarded to Rice Tech, Texas (U.S.A.) in U.S.A. on Sept. 2, 1997 (Patent No. 5663484). This novel rice line is claimed to have been developed by using a novel criterion to determine rice quality; *it has been described in the patent in such a manner that it covers the complete range of features present in the entire germplasm of basmati*, the world famous quality rice of India and Pakistan. As a result, any new basmati variety evolved by any breeding method in India (or elsewhere) is bound to fall within the range of, *e.g.*, plant height, maturity duration, grain size, grain quality, etc., protected by the above patent. Therefore, it is feared that this patent will adversely affect at least the export of Indian basmati.

Obviously, the patentability of a subject matter depends not only on the patent laws of a country, but also on their currently accepted interpretation. *The implications and interpretations of the various provisions of patent act of a country require specialist patent attorneys, who are helpful in filing of patent applications, contesting/defending such applications and in enforcing the rights accruing from patents to the inventors.* Therefore, the objective of this discussion is limited to give the reader a general idea of patents and other forms of protection available for intellectual properties so that expert legal help could be obtained for achieving the desired protection.

5. **Disclosure.** The inventor is required to describe his invention in sufficient detail so that a person of normal skill is able to reproduce it. In case of biological entities, already known organisms may be simply named. But if they have been genetically modified, the nature and the method of modification has to be described fully. In addition, a sample of the microorganism, cell line, etc. being patented may be required to be deposited in the designated culture collection. The deposited material serves the following purposes. (1) It is used as a reference in cases of disputes concerning its novelty or unauthorized use. (2) Further, it serves as a source for the microorganisms, etc. to the authorized users.

A patent may be viewed as a contract between the society and the inventor wherein the inventor discloses his invention in return for the protection granted to him by the society to control the commercial aspects of his invention to the extent that it is not detrimental to the society. The disclosure of an invention gives an opportunity to other inventors to improve upon the various features of the invention so that it becomes more efficient and/or useful. This, in turn, results in scientific and economic progress of the society/nation.

41.4.2.2. *Limits of A Patent.* A patent is limited both in time and space. The two basic limitations of patents are (1) limitation of time and (2) limitation of space. *A patent its is valid for a specified period of time from the date of its award;* in most countries this period is 15–20 years: this constitutes the ***limitation of time***. The Indian Patent Act (1970) grants protection for 7 or 14 years. There is a strong argument for an adequately longer protection period on the grounds that in several cases, *e.g.*, pharmaceuticals, it may take (in various tests and scaling up) up to 10 years from the time a patent is awarded to the time the product reaches market. The patent holder, therefore, should be allowed sufficient time to benefit from his invention. In addition, *a patent is valid only in the country of its award;* it is not valid in other countries; this is the ***limitation in space***. A group of nations may agree to honour the patents awarded by any member country, *e.g.*, in European Economic Community. WTO has a similar provision in that a patent awarded by WTO will be valid in all member countries.

41.4.2.3. Procedure of Patenting. An inventor files a properly prepared application (according to the prescribed proforma) with the patent office of the concerned country. The application is scrutinized and assessed by patent officials; if found unsuitable for patenting, it is returned to the inventor along with the reasons therefor. The inventor may withdraw the application, modify and resubmit it or submit it with an explanation of the objections raised by the patent office. If an application is considered suitable for patenting, the invention along with adequate details of the desired patent is published for the information of all concerned; in India, this is done 18 months after the date of filing of the application. Anyone who wishes to challenge the award of patent can do so within a specified period of time, *e.g.*, within four months in India.

In case a patent application is not challenged the patent is awarded immediately after the expiry of this period and is said to be sealed. But if a patent is challenged, the arguments and counter-arguments of both the applicant and the person challenging the application are heard by a competent authority of the patent office and a final decision is taken on the award of patent. Thus if a patent application is rejected due to a contest following its publication, the main features of the invention stand disclosed. The inventor can not now resort to the option of trade secret. Therefore, it is in the interest of an inventor to ensure, before filing a patent application, that the application is not likely to be rejected at least on account of a contest by a third party.

41.4.3. Copyright

Certain intellectual properties are not patentable; they are protected by copyright. Examples of such properties are authored and edited books, audio and video cassettes, etc. A person holding the copyright to, say, a book has the right to exclude others from reproducing the book in any form. The copyright of a book may be held by the author, editor or the

publisher. Recently, computer software has been included in the list of copyrightable properties [protected under the Information Technology Act (2000)]. The copyright is limited both in time and extent: it provides protection for a specified period, and only from reproduction as such of the copyright material either in toto or in part. It, however, does not prevent another person from using either the idea or the information contained in a copyright material. In case of biotechnology, copyright protection is available for DNA sequences. But one may get around this protection by designing alternative sequence to encode the same protein taking advantage of genetic code degeneracy.

41.4.4. Plant Variety Protection (PVP)

Plant varieties and animal breeds are developed through years of painstaking and scientifically planned work. These entities, therefore, should be regarded as intellectual properties of the breeders who have developed them. It may be argued that these entities are essentially derived from naturally occurring lines, but they usually represent a considerable reorganization of the existing gene combinations and skillful selection work. Many countries recognize plant varieties as an intellectual property and grant a protection to them through a patent or a suitable form of plant breeders rights (PBR) (Section 41.7).

In U.S.A., the following three different systems are available for protection of IPR related to plants. ***The Plant Patents Act (1930)*** covers varieties of asexually propagated crops, *e.g.*, ornamentals and fruit trees.***The Plant Variety Protection Act of 1970*** is US version of the plant breeders rights system followed by European Union and several other countries. ***The Utility Patents Act (1985)*** was originally meant to cover man-made industrial inventions and processes. 'Nonobviousness' is the main criterion of utility patents. Patents to plant varieties are now being granted under the provisions of this act (during 1997–98, 55 patents were granted to maize varieties and 40 for soybean varieties). *Utility patents are considered to be the most powerful and the most expansive in scope of their coverage; a single patent may cover several varieties, an entire species/genus, genes/proteins or technology and processes.*

41.5. INTERNATIONAL HARMONIZATION OF PATENT LAWS

Patents have only territorial validity, and obtaining patents is costly and time consuming. Therefore, IPR protection in more than one country requires patents to be taken in each country, which multiplies the cost involved. In addition, patent laws of different countries are variable. In view of these, developed countries have been trying to harmonize patent laws of different countries and also to find acceptable means of extending the territorial validity of patents.

The first concrete effort in this direction was the Paris Convention for the Protection of Industrial Property signed in 1983. It established equal protection of industrial IPR under the laws of member countries for both nationals and residents of other member countries of the convention. It also allows inventors to claim priority in all the member countries by filing a patent application initially in one member state. The Paris Convention has 100 member states; *India has joined the Paris Convention on December 7, 1998.*

The provisions of Paris and subsequent conventions on IPR are administered, but not enforced, by the World Intellectual Property Organization (WIPO), Geneva. WIPO operates

by asking member states to ratify a convention and to introduce the agreed basic principles into their national laws.

The European Patent Convention (EPC) began to operate in 1978 and has 17 member states. EPC was the first to introduce specific provisions for biotechnology inventions, including (1) the need for depositing cultures of microorganisms for which patents are sought and (2) exclusion of plant and animal varieties bred through classical methods from patent coverage.

41.5.1. TRIPs

The TRIPs (Trade Related Intellectual Property Rights) agreement, which forms a part of the Uruguay Round to GATT (General Agreement on Tariffs and Trade; signed by India and other states), is to date the most comprehensive multilateral agreement on IPR; it became effective on January 1, 1995. The provisions of GATT are administered and enforced by World Trade Organisation (WTO), Geneva. The member countries of WTO are obliged to meet all the articles of TRIPs. They have been given a period of 5 years to suitably ammend their IPR laws: the period is extendable by another 5 years for the least developed countries. The provision of TRIPs cover a variety of intellectual properties, including patents and protection of new varieties of plants. Each member country has the option to frame its own patent laws within the broad framework defined in the GATT agreement (Ganguli, 1998).

Pending modification of patent laws as per TRIPs provision, the developing countries are expected to provide for a 'mail box' protection [Article 70.8(a)]. Under this provision, such a country will accept patent applications for products related to pharmaceuticals and agricultural chemicals from January 1, 1995, and keep them for consideration after the patent laws are suitably ammended. These countries are also required to guarantee an exclusive marketing right for 5 years to each invention, which is the subject matter of one of the above patent applications provided a patent for the same has been granted and marketing approval has been obtained for the same product in another member state after January 1, 1995 (Article 65) (Ganguly, 1998).

41.5.2. India and TRIPs

In 1997, U.S.A. complained to WTO that India has failed to meet the basic commitments to TRIPS. The Dispute Settlement Body of WTO observed that India has failed to provide the 'mail box' system of protection to the concerned products, and to establish a system for the grant of exclusive marketing rights to such patents. Ultimately, India has been given time till April, 1999 to make the above provisions, failing which U.S.A. could call for appropriate sanctions.

India is required to change its patent laws as per the broad framework of TRIPs latest by 2004. The Indian Patent Act (1970) has now been ammended by the Indian Patents (ammedment) Act (1999); the ammendments, listed below, came in force on January 1, 1995.

1. Product patents are allowed, except for some specified medicines/drugs.
2. A provision for grant of 'exclusive marketing rights' (Section 41.5.1) has been made upto December 31, 2004.

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

protection. The role of civil judicial system, therefore, becomes a critical input in the issue since it has to arbiter all such disputes between the two opposing parties. The judicial system also comes into play in cases brought before it for the enforcement of various IPRs. There is enough evidence that at least US judiciary has become more and more liberal in the interpretation of various requirements for a subject matter to be patentable. One can only hope that the judiciary will strike a just and equitable balance between often conflicting interests of the inventor and the society so as to simultaneously promote both biotechnological inventions as well as the welfare of humanity.

41.6.5. IPR and Developing Countries

It may be pointed out that biotechnological inventions demand huge financial inputs. Therefore, developed nations hold a great edge over developing nations in terms of obtaining biotechnological and other high technology patents. Patent activity is greatly concentrated in Europe, U.S.A. and Japan. In these three countries, over 90% of the patent applications are filed (both of total applications and of applications in high technology areas, including biotechnology) by EPC states, Japan and USA Table 41.1).

In India, the average total number of patent applications filed each year during the period 1974-1994 was merely 3,500; this rose to nearly 5,000 in 1995. (In contrast, the global number of new applications during 1994 was 629,611.) A scrutiny of the patents awarded during 1974-1994 reveals the major players to be transnational companies like Hindustan Lever, Hoechst, Johnson & Johnson, Sandoz, CIBA, Colgate, Palmolive, Pfizer, Nestle and Lucas. Very few Indian companies like Bajaj had patented their innovations. More recently, other national companies like Dr. Reddy's Laboratories, Ranbaxy, Lupin Laboratories have begun patenting their innovations. But MNCs like Nordisk, Eli Lily, BASF, Englehart, etc. have also begun aggressive patent filings in India.

TABLE 41.1

The share of European Patent Convention (EPC) states, Japan, U.S.A. and others in the patent applications made during 1995 and 1996 in European Patent Office (EPO), Japanese Patent Office (JPO) and US Patent and Trademark Office (USPTO) (based on Ganguli, 1998)

		Share (%)		
Patent applications filed in EPC States		***Japan***	***U.S.A.***	***Others***
		Total applications		
EPO	50	18	29	4
JPO	~4	~90	~5	<1
USPTO	16	20	56	8
		High Technology applications		
EPO (17.2)*	33	25	39	3
JPO (13.4)	~3	90	6	~1
USPTO (22.5)	10	24	57	8

* Per cent of total patent applications filed.

It is feared that high biotechnological innovations that require huge financial resources and a very high degree of skill (scientific and otherwise), sophistication, motivation and commitment would further increase the gap in IPR holdings of developed and developing nations. In addition, holding an IPR and benefiting from it are two entirely different issues (see, later). Therefore, India needs to do many radical things and at a rapid pace in order to withstand the economic burdens imposed by the changing IPR scenario (Section 41.13).

TABLE 41.2

Some broad patents granted in U.S.A. (except the one with EPO prefix) for plants, traits and technology processes (based on Gupta, 1996)

Patent awarded to	*Patent Number*	*Subject of Patent*
	Plant Patents	
W.R. Grace and Co.	5, 519, 135	All transgenic cotton*
	EPO 0, 301, 749	All transgenic soybeans**
Calgene, Inc.	5, 188, 958	All transgenic plants of *Brassica* family (*Agrobacterium*–mediated transformation only)
DNA Plant Technology	5, 262, 316	All transgenic pepper (genus *Capsicum*)
	Plants with Specific Traits	
Dekalb Genetic Corp.	5, 258, 300	All transgenic plants with increased lysine content
Plant Genetic Systems	5, 254, 799	All transgenic plants with *cry* gene of *B. thuringiensis* (using *Agrobacterium*)
Pioneer Hi-Bred	5, 276, 264	Sunflower with low level of saturated fatty acids
	Technology/Process	
Enzo Biochem, Inc.	—	'Antisense' RNA technology
W.R. Grace and Co.	5, 004, 863	Gene gun method of genetic engineering of soybean
Mycogen Corp.	5, 380, 831	Any method of modifying the *cry* gene of *B. thuringiensis*

* Revoked but still effective till all the appeals are exhausted.
** Challenged by RAFI (Rural Advancement Foundation International), Canada and others.

41.6.6. Broad Patents in Biotechnology

Most patents in biotechnology, especially agricultural biotechnology, are rather broad in nature (Table 41.2). The most widely discussed case concerns patent protection of all kinds of transgenic cotton granted in October, 1992 to Agracetus (Middleton, U.S.A.), a subsidiary of W.R. Grace and Co. A similar patent to Agracetus was granted in India in 1991. This patent was challenged and the USPTO revoked it in December, 1994 as a consequence of its reexamination. However, the final position of this revocation will be clear only after Agracetus (U.S.A.) has exhausted all the opportunities of appeal against it, and till such time the patent will be effective and operative. In India, the patent was revoked in 1994 due mainly to the efforts of ICAR and DBT, New Delhi.

It is a general practice to prepare the patent applications in a manner such that the widest possible coverage is available. Such broad patents are considered morally unacceptable and fundamentally inequitable. They clearly demonstrate that the IPR protection system went out

of control in these cases. Such protections, if allowed and continued in future, will work only for financially powerful corporations. It is feared that ultimately these corporations will acquire monopoly control over biotechnological modifications of even such crops that feed and sustain mankind. They may even acquire legal right to determine the future of high-tech research for the entire segment of agriculture and plant breeding and, thereby, dictate terms and conditions for future agricultural research. Such a situation would be detrimental to scientific and technological progress, and would pose a threat to global food security.

41.6.7. The Patent Imbroglio

Development of genetic engineering products requires several technologies and/or raw materials. For example, production of a transgenic plant would require the following: (1) an otherwise outstanding variety of the concerned crop, (2) suitable promoters and/or enhancer sequences, (3) appropriate reporter genes, (4) the gene specifying the concerned trait, (5) appropriate genetic transformation method and, sometimes, (6) a specific technology, *e.g.*, *antisense* technology for suppression of endogenous genes. At the time of initiation of the project to produce a transgenic plant, many of the above would have been patented, while the ownership of some others may be uncertain.

Products developed using a patented technology/raw material can not be commercialized without a licence. In some cases, however, a licence may not be available as it may have been already granted to another party on an exclusive basis. Patent/licence holders generally do not raise questions of infringement during the research and development phase, and prefer to wait till the product (in this case, a transgenic plant) is ready to be marketed. At that time, the patent/licence holders initiate legal proceedings claiming infringement.

For example, DNA Plant Technology (U.S.A.) developed 'Endless Summer' transgenic tomato by using the following: (1) antisense technology, (2) *Agrobacterium tumefaciens*-mediated genetic transformation, (3) CaMV *35S* promoter, (4) selectable marker *nptII* with its promoter and terminator and (5) the ACC synthase gene; all these are protected by patents. DNA Plant Technology was to release 'Endless Summer' in 1996, but it faced difficulties due to the use of patented subject matters. It is trying to substitute some of the components used to produce 'Endless Summer', *e.g.*, use of *ALS* (acetolactate synthase gene providing resistance against several herbicides) selectable marker system in place of *nptII*, etc., and to obtain licences for the others. (*ALS* gene has been patented by DuPont, and DNA Plant Technology has entered a collaboration with DuPont.).

Obviously, it is in the interest of the inventor to have a very clear and precise idea of the IPR positions of the various materials/processes being used by him in his R&D efforts and to take appropriate steps to acquire licence, etc., where necessary, much before the product is ready for marketing. Any misinformation/miscalculation in this regard may have costly repercussions later. The various options available to an inventor in cases of use of patented processes/products in an invention are as follows: (1) licence of the product/process may be obtained, (2) the inventor may enter into a collaboration with the patent/licence holder, (3) an effort may be made for cross-licensing, (4) merger/takeover of the company holding the license, and (5) replacement of the patented technology/product another available technology/product.

It can be easily seen that IPR regimes have greatly complicated the commercial aspects of biotechnological products. In several cases, these complications have resulted in legal battles, and also in delayed marketing of the products. All these tend to dampen the pace of biotechnological innovations. They also tilt the balance in favour of giant corporations, which can allocate adequate financial and other resources to manage their IPR related issues and to safeguard their financial interests.

41.7. PLANT BREEDER'S RIGHTS (PBR)

Plant breeders rights are the rights granted by the government to a plant breeder, originator or owner of a variety to exclude others from producing or commercializing the propagating material of that variety for a minimum period of 15–20 years. A person holding PBR title to a variety can authorize other interested persons/organizations to produce and sell the propagating material of that variety. He should set reasonable terms for such transfers of PBR titles or for the sale of the propagating materials; otherwise the government can grant licenses of the titles in public interest. It is important that the object of protection in PBR is the variety, and that genetic components and the breeding procedures are not protectable. In addition, PBR systems also contain some form of 'breeders' exemption and 'farmers' privilege (Sections 41.7.5 and 41.7.6).

41.7.1. Historical

A patent act to provide patents on plants was first introduced in Germany in 1866. In the beginning of the present century, legislations for patenting plants were subsequently introduced in other countries, including U.S.A. where provisions for patenting varieties of asexually propagated crops were made. The International Organisation for Plant Variety Protection (ASSINSEL) was established in 1938 with the objective of persuading governments of different countries for introducing laws to protect plant varieties. Several countries, particularly in Europe, developed their own systems of PBR.

The most significant event in the development of PBR systems was the effort to harmonize PBR laws of different countries through UPOV (Union Internationale pour la Protection des Obstentions Vegetales, International Union for Protection of New Plant Varieties). The first UPOV convention was signed in 1961 in Paris; in 1993, it had 24 member states *e.g.*, Australia, Belgium, Canada, France, Germany, Israel, Italy, Japan, South Africa, Switzerland, U.K., U.S.A., etc. The member states of UPOV adopt PBR systems conforming to the broad framework agreed upon in the convention. In addition, nationals of one member state have rights in other member countries.

41.7.2. A Comparison among UPOV Acts, PPVFR Act and Patents

The UPOV member countries were following the UPOV 1978 Act. This act is now revised as UPOV 1991 Act, which came into force on April 24, 1998. The UPOV 1991 Act has strengthened the PBR in comparison to UPOV 1978 Act and has made PBR more comparable to a patent (Table 41.3). India has enacted the Protection of Plant Varieties and Farmer's Rights Act (2001). The features of the UPOV acts, the PPVFR Act and patents are compared in Table 41.3.

TABLE 41.3

A comparison of UPOV Act (1978) with UPOV Act (1991), PPVFR Act (2001) and Patents

Feature	*UPOV Act (1978)*	*UPOV Act (1991)*	*PPVFR Act (2001)* *	*Patent*
Protection coverage	Plant varieties of nationally defined plant species	Plant varieties of all plant genera and species	Varieties of nationally specified genera and species	Inventions
Requirements for protection	1. Distinctness 2. Uniformity 3. Stability	1. Novelty 2. Distinctiveness 3. Uniformity 4. Stability	1. Novelty** 2. Distinctiveness† 3. Uniformity 4. Stability	1. Novelty 2. Inventiveness 3. Nonobviousness 4. Industrial application and usefulness
Duration of protection	Minimum 15 yr	Minimum 20 yr	Maximum 15 yr for extant varieties and new varieties of crops; 18 yr for varieties of trrees and vines	17–20 yr (OECD)+
Scope of protection	Commercial use of the ***reproductive*** material of protected variety	Commercial use of ***all material*** of the protected variety	Commercial use of all material of the protected variety	Commercial use of protected subject matter
Breeders' exemption	Yes	Yes, *except for* ***essentially-derived*** **varieties**	Yes, except for essentially-derived varieties, and use as parents of hybrid varieties	No
Farmers' privilege	Yes (in practice)	Optional; left to the national laws	Yes, as 'farmers' rights'; more extensive than in UPOV Act (1978)	No

* PPVFR Act, 2001, The Protection of Plant Varieties and Farmers' Right Act, 2001.

** A variety not in commercial use for more than one year in India, or 4 years (6 years in case of trees and vines) outside India.

† In case of extant varieties; distinctiveness, uniformity and stability.

+ OECD, Organization for Economic Cooperation and Development.

The Protection of Plant Varieties and Farmer's Right Act (2001) is similar to UPOV Act (1978) in some respects, has same features of UPOV Act (1991) and is unique in respect of some of its other features. PPVFR Act (2001) is similar to UPOV Act (1978) in the following respects: (1) protection of varieties of nationally recognized plant species, (2) the duration of protection is 15 years or more (18 years in the case of trees and vines), and (3) provision for

farmers' privilege (Section 41.7.7). But PPVFR (2001) is comparable to UPOV Act(1991) in the following respects: (1) requirement of novelty, distinctiveness, uniformity and stability for registration of variety, (2) protection extended to commercial use of all the material of the protected variety, and (3) essentially-derived varieties being subject to PBR protection granted to the concerned initial varieties.

The PPVFR Act (2001), however, has certain unique features that are not provided for in the UPOV Acts (1978, 1991); these features are as follows: (1) registration of extant varieties, (2) registration of farmer's varieties, and (3) recognition of farmer's right (as discussed in Section 41.7.7) and provision for monetary compensation for these rights from the National Gene Fund; India is the first country in the world to make a concrete legal provision for monetary compensation for farmer's rights. In addition, (4) the PPVFR (2001) exends the farmer's privilege of UPOV Act (1978) and permits farmers to 'exchange, share or sell' their farm produce, including seed, except as branded seed. (5) PPVFR (2001) also provides protection to farmer's from innocent infringement of PBR.

41.7.3. Requirements for PBR

Under the provisions of UPOV 1991 Act, a plant variety must satisfy the following four criteria for protection: (1) novelty, (2) distinctiveness, (3) uniformity and (4) stability. The criterion of ***novelty*** requires that a variety should not have been commercially exploited for more than one year before the grant of PBR protection. ***Distinctiveness*** required that the new variety must be distinguishable from other varieties by one or more identifiable morphological, physiological, or other characteristics. The new variety must be uniform in appearance under the specified environment of its adaptation (***uniformity***). Further, the new variety must be stable in appearance and its clonal characteristics over successive generations under the specified environment to satisfy the criterion of ***stability***.

41.7.4. The Extent of Protection by PBR

The provisions of UPOV 1991 Act offer the following protections to the concerned variety.

(*i*) Production for commercial purposes, offering for sale and selling all material becomes the exclusive right of the holder of the PBR-title.

(*ii*) A grower may be allowed to reserve a portion of his harvest for use as seed for his own next crop without the permission of the holder of the PBR-title. *This is called **farmers' exemption;** but a farmer who does this is not allowed to sell such material to anyone else.*

(*iii*) Exchange of propagating material of different cultivars between farmers is not allowed.

(*iv*) The minimum period of protection prescribed is 20 years. Several UPOV member states have established a longer period of protection of 20–25 years, with 30 years in France for inbred lines of maize, and for clovers and a few grasses.

(*v*) The use of propagating material from a protected cultivar for scientific purposes is not dependent on permission of the holder of the PBR-title.

(*vi*) The use of protected cultivar for the creation of genetic variability for plant breeding purposes is not dependent on permission of the holder of the title.

(*vii*) PBR protection does not cover breeding methods.

(*viii*) PBR protection covers the new variety, but does not protect the parents of the variety, except in the case of hybrid varieties.

41.7.5. Breeder's Exemption

Under PBR regime, the use of material of a protected variety (***the initial variety***) for the development of new varieties is exempted from protection. The PBR for these new varieties will be of the breeder who developed them, and the holder of PBR-title of the initial variety will have no claim to it. This provision is called ***breeders' exemption.*** Under the UPOV 1978 Act, all new varieties evolved using a protected variety were exempted from protection under this provision. But UPOV 1991 Act has somewhat limited the scope of breeder's exemption by bringing 'essentially-derived' varieties under the cover of PBR protection granted to the initial variety. An ***essentially-derived variety*** has been defined as a variety predominantly derived from the initial variety, which retains the expression of the essential characteristics from the genotype or combination of genotypes of the initial variety. Thus a variety produced by, say, mutation or transfer through backcross method/integration by genetic transformation of a single gene will be considered as an 'essentially-derived variety', and will be protected under the PBR-title granted to the initial variety. The breeder of such a variety will, therefore, be required to obtain permission from the PBR-title holder of the initial variety.

Breeder's exemption in one form or the other is available in all PBR systems. The accessibility of protected varieties for use in breeding programmes is generally appreciated by plant breeders as it allows a free gene traffic from one breeder to the other. However, the parental inbreds/lines of a protected hybrid variety are also protected materials and, as such, they are not accessible for use as breeding materials.

41.7.6. Farmer's Privilege

PBR systems generally allow the farmers to use the material of a protected variety produced on their farm for planting of their new crop without any obligation to the PBR title holder. This exemption is usually referred to as ***farmers' privilege***. Under the UPOV 1978 Act, there was explicit provision for farmer's privilege. But in the proposed UPOV 1991 Act, this privilege has been made 'optional' and each UPOV member state can either allow or disallow this privilege. It should be clearly understood that farmers privilege applies to the use of seed produced by a farmer for sowing 'his own' fields. PBR, however, does not allow farmers to exchange seeds of protected varieties produced on their farms.

Farmer's privilege is a very important provision for countries like India, where over 90% of the total cropped area is sown by seeds produced by the farmers themselves. In addition, a majority of the farmers are poor and will be subject to unjust economic burden if they are forced to pay a royalty on the seed produced and used by them. The infrastructure of seed industry does not allow the option of use of new seed every year even if the farmers could be made, by some miracle, capable of the same.

41.7.7. Farmer's Rights

Agriculture began some 10,000 years ago. During this vast period of time genetic resources have been selected, developed, used and conserved by farmer families and farming communities of, particularly, the gene-rich developing countries. These same materials have been and are being collected, conserved and used as raw materials to evolve the modern high yielding varieties of various crops. Seed sales of these improved varieties earn huge profits for the seed corporations.

It has been argued that the farmers should be allowed a share in this profit in recognition of their contribution by way of the development of germplasms of the various crops. This has been recognised by FAO (Resolution no. 5/89) as ***farmer's rights,*** which arise from the past, present and future contributions of farmers in conserving, improving and making available plant genetic resources, particularly in the centres of origin/diversity. It has been emphasized that the farmer's rights should be obligatory and should not be relegated as privileges.

The key questions relating to farmers rights remain as to whom to reward, to what extent and in what manner. It has been suggested that tribal people, rural communities and traditional farming families deserve consideration. The quantum of reward has also been debated, and one suggestion is for 5% of the profits. However, the farmer's rights are yet to be legalised in any country, and their implementation remains a far cry.

41.7.8. The Need for PBR

The concept of PBR originated in the developed countries, where private companies have been important/major players in plant breeding and seed production/marketing. The main considerations for the development of PBR systems were as follows. (1) It allows breeders to benefit from the varieties developed by them, which, in turn, encourages plant breeding activities. (2) Private sector is encouraged to invest in plant breeding and seed industry. Finally, (3) Development of a new plant variety is as much of an innovation as invention of a machine/product. Therefore, a plant variety should be regarded as an intellectual property, the rights to benefit from which need legal protection.

The situation in India is markedly different from that in west in that plant breeding activity is largely carried out by public sector institutions (Agriculture Universities and ICAR Institutes/Centres), and private sector is yet to emerge as a major player. But plant breeding activities in the private sector are on the increase, and with the entry of giants like Monsanto, U.S.A., an upward surge in the activities may be anticipated. It has been argued (Ghijsen, 1998) by some that Asian countries should evolve their own system of PBR (1) that recognizes community interests, *e.g.*, the informal seed system of open-pollinated varieties, and (2) that extends, in public interest, the concept of "essentially-derived" variety to varieties developed from unprotected varieties (used as initial varieties) developed by public institutions. India has now enacted its own PBR law called Protectioin of Plant varieties Farmer's Rights Act, 2001 (PPVFR, 2001).

41.7.9. The Protection of Plant Varieties and Farmer's Right Act, 2001 (PPVFR, 2001)

The Protection of Plant Varieties and Farmers' Act, 2001 (PPVFR Act, 2001), was passed

on August 9, 2001 by the Lok Sabha. The Act aims "to provide for the establishment of an effective system for protection of plant varieties, the rights of farmers and plant breeders and to encourage the development of new varieties of plants". The main features of this Act are briefly summarised below.

1. Registration of 'farmer's varieties', 'extant varieties' and 'new varieties' of such genera and species as notified in the Official Gazette by the Central Government. A ***farmer's variety*** is a variety that has been traditionally cultivated and evolved by farmers, or is a wild relative or land race in common knonwledge of farmers. An ***extant variety*** is a notified variety or a farmers variety that is in public domain. *Registration of the extant varieties will be done within a specified period and suject to their meeting the criteria of distinctiveness, uniformity and stability.*
2. A new variety shall be registered if it meets the crieteria of novelty, distinctiveness, uniformity and stability. The criterion of ***novelty*** requires a variety to be in commecial use for less than one year in India, or 4 years (6 years in case of trees and vines) outside India.

   The variety must be distinguishable for at least one essential characteristic from any other variety whose existence is a common knowledge in any country (***distinctiveness***). ***Essential characteristic*** is a heritable trait that contributes to the 'principal feature, performance or value of the plant variety'. Further, a ***variety in 'common knowledge'*** means any variety for which an application for grant of PBR or for entering the variety in the official register of varieties has been filed in any convention country. The criteria of uniformity and stability are essentially comparable to those for UPOV (1991).
3. Any variety that involves any technology including 'gene use restriction' and 'terminator technologies', which is injurious to life or health of human beings, animals or plants shall not be registered.
4. A variety that has been 'essentially-derived' from an 'initial variety' can be registered as a new variety. The breeder of such a variety must obtain authorization from the breeder of the initial variety since the essenially-derived variety is subject to the PBR of the initial variety. The definition of an ***essentially-derived variety*** is comparable to that given for UPOV Act (1991) with an additional clarification that such a variety must be distinguishable from the'initial variety' and otherwise conform to the latter in the expression of heritable essential characteristics.
5. The duration of protection of the varieties will be 15 yr for the extant varieties, 18 yr for varieties of trees and vines and 15 yr for varieties of other crops.
6. Registration of a variety confers on the breeder of that variety or his successor or his agent or licensee an exclusive right 'to produce, sell, market, distribute, import or export the variety'. Apparently, the protection is not limited to seed of propagules and extends to all material of the protected variety.
7. The provision for *researcher's rights allows any person to use any registered variety for research and for creation of new varieties, except essentially-derived varieties, without paying any royalty to the PBR holder.*

8. The Act recognizes the *farmer's rights* in the following respects.
   (*i*) Registration of farmer's varieties.
   (*ii*) Reward from the 'national gene fund' for those farmers who are 'engaged in the conservation of generic resources of land races and wild relatives of economic plants and their improvement through selection and preservation' provided that the 'materials so selected and preserved have been used as donors of genes in varieties registered under this Act'.
   (*iii*) Freedom of farmers 'to save, use, sow, resow, exchange, share or sell' their 'farm produce, including seed (except for 'branded seed') of a variety protected under this Act in the same manner' as they were 'entitled before the coming into force of this Act'.
   (*iv*) Requirement for the breeder to disclose to the farmers the expected performance of the variety under given conditions; the farmers can claim compensation if this expectation is not fulfilled.
9. The procedure for making a 'claim attributable to the contribution in the evolution of any variey' and seeking reward from the 'gene fund' has been specified.
10. The Central Government is to constitute a National Gene Fund from the earnings of benefit sharing of registered varieties, compensations deposited in the fund, and contributions from national and international organizations. The gene fund shall be used for paying compensation to communities for their contributions to the development of a variety, for benefit sharing (as determined under the provisions of this Act) and for 'conservation and sustainable use of generic resources' and for 'strengthening the capability of Panchayats in carrying out such conservation and sustainable use'.
11. Compulsory license may be granted after 3 years of registration of a variety if seed of the variety is not available to the public either in adequate quantity or at a reasonable price.
12. The Central Government shall establish the Protection of Plant Varieties and Farmer's Rights Authority. It shall be the duty of the authority to promote the development of new varieties of plants and to protect the rights of the farmers and breeders.
13. The Central Government shall establish a Plant Varieties Registry for the registration of plant varieties. The registry shall maintain a 'national register of plant varieties' containing names of all registered varieties, names and addresses of their breeders and other relevant details.
14. The breeder shall be required to deposit specified quantities of seeds/propagules of the registered variety as well as its parental lines in the National Gene Bank as specified by the Protection of Plant Varieties and Farmer's Rights Authority.
15. Citizens of convention countries will have the same rights as citizens of India under the Act. A convention country is a country that is member of such an international

convention for protection of plant varieties to which India is also a member, or a country with which India has agreed to grant PBR to citizens of both the countries.

16. Application for registration of a variety may be made in India wihin 12 months from the date of application for registration of the same plant variety made in a convention country. If such a variety is registered, the date of registration in India shall be the date of application in the convention country.
17. The rights of PBR holder 'shall not be deemed infringed by a farmer who at the time of such infringement was not aware of the existence of such right'.

It may be pointed out that the two provisions of extending recognition to informal seed systems like those of open-pollinated varieties, and extension of the provision of "essentially-derived varieties" to unprotected public varieties (Ghijsen, 1998) deserve serious consideration. In addition, declaration of parentage of the variety should be mandatory for protection.

41.7.10. Benefits from PBR

The benefits from PBR regime are briefly summarized as follows.

1. The opportunity to breeders of obtaining profits from varieties developed by them will act as an incentive in promoting plant breeding research.
2. It encourages private companies to invest in plant breeding activities.
3. It will enable access to varieties developed in other countries and protected by IPR laws.
4. Increased competition among various organizations engaged in plant breeding is likely to be beneficial to both the farmers and the nation.

41.7.11. Disadvantages from PBR

1. PBR will encourage monopolies in genetic material for specific traits.
2. It suppresses free exchange of genetic material and may encourage unhealthy practices.
3. The holder of PBR-title may produce less seed than the demand in order to increase prices for achieving more profit.
4. Farmer's privilege to resow the seed produced by him may become gradually diluted/eliminated.
5. PBR may result in increased cost of seed, which will be burdensome to the poor farmers of India, and would limit the benefits from new varieties to a small segment of rich farmers.

41.8. CHOICE OF IPR PROTECTION

An intellectual property can often be protected in more than one way, *e.g.*, as a trade secret, patent or PBR. The decision has to be made by the inventor as to which form of protection would be the most appropriate for his invention. This decision will be influenced by several factors, some of the more important of which are summarised below.

1. **Nature of Intellectual Property.** The type of intellectual property would often have the most critical impact. For example, while a cell line or a bacterial strain can be kept as a trade secret, a transgene or a plant variety can not.

2. **Pace of Technology Development.** If the pace of development is rapid, a trade secret approach would be preferable to patenting.

3. **Associated Costs.** The costs associated with the acquisition and management of IPR is very important consideration. Generally, maintaining a trade secret is costlier than obtaining a patent. But enforcing a patent, however, is often rather costly. In comparison to a patent, acquisition of PBR-title is much less expensive and complicated.

4. **Security Considerations.** In the long run, it may become exceedingly difficult to maintain a trade secret. Therefore, one may often look for patents to protect an intellectual property.

5. **Need to Show Inventions.** Patents can be shown to investors for commercialization of the intellectual property without compromising the IPR. The same can not be done for trade secrets.

6. **Duration of Protection.** Patents offer protection for a specified duration *viz.*, up to 20 years. If protection is sought for a longer duration, trade secrets are the only available option. A PBR protection, if available, would be for a little longer duration (20 or more years) than that from patents.

7. **The Type of Protection Sought.** Protection of plant varieties by a patent provides a more rigid control to the inventor (breeder) than does a PBR title.

41.9. MANAGEMENT OF IPR

IPR is ordinarily acquired in the anticipation that the concerned intellectual property can be commercialized. A mere holding of IPR does not guarantee profit generation from the same. Often considerable research and development (R&D) effort may be needed to make an intellectual property marketable. For example, following the patenting of a new pharmaceutical, say, an antibiotic, it has to undergo clinical trials and other tests and clearances before it can be allowed for marketing. In addition, the production process has to be scaled up. Therefore, the holder of IPR has to manage the IPR portfolio in such a manner so that it generates some profit. IPR management involves the following activities.

1. Transfer of the IPR appropriately and at optimum value to obtain attractive returns for the expense involved in generating the intellectual property.
2. Establishment of collaborative linkages to facilitate exploitation of the IPR.
3. Monitoring infringements of the IPR and enforcing one's rights where necessary.
4. Renewal of patents and designs periodically in every country where they have been granted.
5. Quantitative evaluation of factors such as R&D investments to the royalty ratio will have to be done periodically. This will enable the IPR holder to decide as to which IPRs are to be renewed in the different parts of the world.

41.10. BENEFITS FROM IPR

1. It encourages and safeguards intellectual and artistic creations.
2. It enables the dissemination of new ideas and technologies quickly and widely; this is achieved by the requirement of disclosure for grant of patents, etc.
3. It encourages investments in R&D efforts.
4. It provides consumers with the results of creations and inventions.
5. It provides increased opportunities for the distribution of the above effects across countries in a manner proportionate to the national levels of industrial and economic development.

41.11. PROBLEMS FROM IPR

1. IPR has encouraged monopolies; many takeovers have been motivated by access to an IPR.
2. The IPR situation in many cases (Section 41.6.7) is quite complicated. Monitoring and tackling the IPR aspects of inventions (1) enhances cost, (2) demands time, attention and effort, and (3) may act as a disincentive for R&D efforts.
3. It is perceived by many as a threat to food security.
4. It may adversely affect biological diversity and ecological balance.
5. It may be detrimental to the livelihood of the poor in developing countries.

41.12. GEOGRAPHICAL INDICATIONS

Geographical indications (GIs) cover such qualities, reputation or other characteristics of a product that could be used to recognize that a product has originated from a particular territory, region or locality. In addition, the quality, reputation or other characteristic of the product should be essentially attributable to the geographical origin of the product. Some examples of products that come under GI are Scotch Whiskey, Champagne and California wines. Suitable laws have to be enacted by concerned countries to avail protection under the provisions of G.I. Such a legislation clearly specifies the products that have been accepted in terms of quality and other characteristics to have originated from given specific localities. The GIs, once enforced by legislation, exclude others from using a GI as a trademark since such a use is likely to mislead the consumer about the place of origin of the product.

The GIs cover agricultural goods, natural products manufactured products, goods of handicraft and even food products. The chief requirement for GI protection is that a given quality, reputation or some other characteristics of the product in question should be essentially attributable to the locality or region of origin of this product. India has enacted the Geographical Indications Act (1999) to claim GI for a variety of goods, including 'basmati' rice. GI protecction is recognised under the provisions of TRIPs of GATT (1994).

41.13. INTERNATIONAL CONVENTION ON BIOLOGICAL DIVERSITY (ICBD)

On December 29, 1993, India and 172 other nations signed the International Convention on Biological Diversity (CBD). This historical treaty recognizes the sovereign rights of nations

over their genetic resources and also for determining access to them based on prior informed consent and linking to transfer of relevant technologies and sharing of benefits.

Earlier to this, India was a signatory to the International Undertaking on Plant Genetic Resources developed by the FAO in 1983; it was adopted by 112 countries. This undertaking was based on the concept that plant genetic resources were the common heritage of mankind. The text of this undertaking is now being harmonized with that of the CBD, and this revised text is expected to become a protocol to the CBD providing a mechanism for its implementation.

The CBD has recognized two outstanding issues that needed resolution as follows: (1) the mechanism for implementing farmer's rights and (2) the status of *ex situ* germplasm collections that were not acquired according to the provisions of CBD, *i.e.*, collected prior to December, 1993. These matters have now been taken up by the FAO Council following a resolution (3/93) adopted by the Conference of Contracting Parties. The International Agricultural Research Centres under the CGIAR (Consultative Group for International Agricultural Research) system have placed their global germplasm collections under the auspices of FAO upon joining the International Network of *ex-situ* collections through an agreement signed on October 26, 1994 (Rana, 1995). India has enacted the Biological Diversity Act (2002), and created a National Biodiversity Authority (NBA), Chennai. The NBA has a mandate to control biodiversity use, and prevent unauthorized transfer of information about the biological resources of the country to a person who is not a citizen of India or a corporate body that is not registered in the country.

41.14. INDIAN RESPONSE TO THE IPR UPHEAVAL

The rapid changes in IPR scenario of the country have taken the scientists and technologists by surprise. This is mainly because the Indian culture and traditions emphasize the sacrifice of individual interests for the benefit of the society at large, while IPR regimes seek to reverse this trend. However, in order to survive in an IPR hungry world, systematic, effective and continued efforts must be made to bring about the following (Ganguli, 1998), and possibly more.

1. Scientists and technologists must be trained to read patents, interpret claims and map claims into prior art so that they are able to provide technical support to the following: (*i*) writing 'world-class' patents based on their innovations, (*ii*) defending patents, (*iii*) formulating opposition/revocation cases, (*iv*) identifing infringements, (*v*) preparing well-focussed R&D programmes, (*vi*) striking collaborations with business houses, (*vii*) technology transfer/liaison offices in the institutions, and (*viii*) evaluating the effectiveness of IPR portfolios.
2. Access to international databases on patents for their technical content, legal status, etc. needs to be ensured.
3. Information scientists need to be trained to extract relevant information from patents granted world-wide in a timely and cost-effective manner.
4. Knowledge databases of our national resources, such as, biodiversity, traditional medicinal and cosmeceutical practices, techniques of our craftsmen, etc. have to be

created and made accessible to various practitioners. This is important as bringing innovations based on traditional knowledge and practices under the IPR regime are current tissues awaiting explosive growth.

5. In order to enhance working and commercialization of patents, a formal patent market' may be set up. This could serve as 'one-stop-shop' for industries and entrepreneurs.
6. Technical personnel may be trained formally as patent attorneys so that they are able to handle the complex techno-legal issues related to patents.
7. Active liaison units with technical expertise in IPR may be established; these would serve as resource centres for various institutions in the country.
8. On-line and up-to-date information on patents filed and granted in India should be made available.
9. Technology mapping based on patent information and human resource (technical/business) databases should be undertaken to create knowledge directories. This would enable the identification of national priorities and formulation of a national science and technology directory.
10. Efficient and effective systems of IPR portfolio management must be evolved to make IPR acquisition a rewarding activity.
11. Educational institutions must introduce IPR into their curriculum in order to generate awareness among students about the meaning of and opportunities due to IPR, and its impact on innovation, trade, industry and the nation.
12. The Indian Patent Office (IPO) must be modernized in every respect so that it is able to perform its functions speedily. It is heartening that the government has already initiated this process.
13. The role of IPO should be widened from a mere governance of the patent system to being a proactive partner in national awareness of IPR and technology/business development.
14. Our institutions will have to evolve a new ethos by setting up frameworks/processes and respond to business-driven R&D functions, identify focussed projects, learn to negotiate terms and at the same time deliver 'world class' scientists and engineers as a part of their academic commitment.
15. A drastic change in the attitudes of scientists/technologists is essential. This calls for appropriate and motivating changes in the working atmosphere, reward-punishment regimes, etc. so that the scientists/technologists/academicians are motivated to adopt a serious and committed work culture.
16. The administrative and civil legal/judicial system needs to be streamlined to be able to handle the huge number of disputes that are likely to arise due to the wider implementation of the various IPR regimes.
17. Our educational system needs to be drastically reformed to produce vibrant, innovative, committed and motivated individuals, especially scientists and technologists.

Questions

1. Define intellectual property and intellectual property rights. Briefly describe the various forms of protection of intellectual property, and discuss the merits and demerits of IPR.
2. What are patents ? Briefly describe the various requirements and the process of award of a patent.
3. Discuss in some detail the protection of biotechnological inventions under the following heads: (1) Biotechnological inventions, (2) Patenting of DNA sequences, (3) Patenting of life forms and (4) Protection of plant materials.
4. Discuss the efforts made for international hormonization of patent laws and the role of TRIPs. What should be the Indian response to the emerging IPR scenario ?
5. Discuss the *pros* and *cons* of patenting life forms and also effects of patenting and commercialization of biotechnological products.
6. What are plant breeder's rights ? Briefly describe the requirements for grant of PBR protection, the scope of protection, breeder's exemption and farmer's privilege.
7. Compare the salient features of UPOV 1978 and 1991 Acts, PPVFR Act (2001) and patents. Discuss the need for a PBR regime in India, and suggest its main features.
8. Write short notes on the following: (*i*) Farmer's rights, (*ii*) Breeder's exemption, (*iii*) Farmer's privilege, (*iv*) International convention on biological diversity, (*v*) Patents, (*vi*) Patenting of life forms, (*vii*) Plant breeder's rights, (*viii*) Intellectual property rights, (*ix*) Management of IPR, (*x*) Indian response to IPR regime, (*xi*) Trade secrets, (*xii*) UPOV, (*xiii*) TRIPs, (*xiv*) Gene patents and genetic resources, (*xv*) Broad patents in biotechnology, (*xvi*) Choice of the form of IPR protection, (*xvii*) Intellectual property, (*xviii*) PPVFR Act (2001), (*xix*) Geographical indications.

Suggested Further Readings

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