This paper discusses about the patentable and non-patentable inventions in biotechnology. It also gives a brief account of the classification of biotechnological inventions, difficulties in legal protection to biotechnological inventions, patentability under the Patent Act 1970 and provisions under TRIPS.

The importance of biotechnology has grown in recent years and biotechnological inventions will have a very significant role to play in future, particularly in the field of food, energy and protection of environment.

But existing patent legislations in most countries are no longer well adapted to secure adequate protection for the invention in this field. The sustained efforts of the International Conventions like World Intellectual Property Organisation (WIPO), European Patent Convention, Paris Convention for the Protection of Industrial Property and Budapest Treaty for Deposition of Microorganisms for the patent procedure to harmonize and modernise the national laws of their member countries have so far not been able to cope up adequately with the situation. However, the TRIPS agreement which is a integral part of GATT has made certain provisions in order to harmonize the patent laws of the member countries in the field of biotechnology.

Biotechnology, in general comprises any technology that uses living entities, in particular animals, plants, or microorganisms or cause organic changes in them. From the very beginning of civilization, man has deliberately selected organisms that improve agriculture, animal husbandry, baking and brewing. However, the human possibilities of intervening in the process of nature or exploiting it, for a long time remained very limited. Only in the middle of last century scientific developments started that led first to a better understanding of genetics and to more effective application of traditional genetics and subsequently in the course of the last decade, to new developments in selecting and manipulating genetic material.

Despite the long standing tradition of biotechnological activities, there is so far no generally agreed definition of ‘term’ biotechnology. However the Office of Technology Assessment of the United States Congress (OTA) has offered a much more detailed definition, according to which, biotechnol-
ogy includes any technique that uses living organisms (or parts of organisms) to make modified products, to improve plants, animals or to develop microorganisms for specific uses.

A more abstract definition can be found in a study prepared under the auspices of the Organisation for Economic Cooperation and Development (OECD) by Bull, Holt and Lilly (1982) in which biotechnology is defined as "The application of scientific and engineering principles to the processing of materials by biological agents to provide goods and services". In this definition, the term "biological agents" refers to a wide range of biological catalysts, particularly to microorganisms, enzymes and animal and plant cells and the concept of "material" includes both organic and inorganic materials.

Classification of biotechnological inventions

Since biotechnology concerns living and non-living matters, the biotechnological inventions can be classified broadly into following categories.

(i) Invention relating to an organism or material *per se* such as

(a) Living entities of natural or artificial origin, such as animals, plants and microorganisms, biological material, such as plasmids, viruses and replicons, and parts thereof, such as organs, tissues, cells and organelles.

(b) Naturally occurring substances from living entities, biological material and parts thereof.

(ii) Invention relating to a process for the creation of a living organisms or production of other biological materials of parts thereof as defined in (i) above.

(iii) Inventions relating to use of such organisms or biological materials.

Difficulties in legal protection to biotechnological inventions

Biotechnological inventions constitute a category of technology that, although of particular economic importance to all countries, has given rise to considerable difficulties in their legal protection. These difficulties are mainly for three reasons. Firstly, it appeared doubtful whether protection should be granted for the inventions relating to living matter since traditionally technology has been understood as an art to cause certain effects in animate matter. Secondly, because of unique features of each living entity, it appeared difficult if not impossible, to describe biotechnological inventions in a manner enabling an expert to repeat the result obtained by the inventor. Thirdly, whether they should be considered as invention or just a discovery or things found in nature.

Because of these problems it was argued that patent laws were unable to provide adequate protection to new varieties of plants. Thus, when an economic need arose for the protection of plant varieties, a special system of protection, International Union for the Protection of new Varieties of plants (UPOV), outside the area of patent laws, was also established at international level in a number of countries. On the other hand, after decades of legal uncertainty, it was only in the late 1960 and in the 1970s, the highest courts of some developed countries recognized, under certain conditions, the principles of patent protection for invention in the field of living matter. In addition, specific legal developments, originating in Europe, led to a situation in a number of countries where plant and animal varieties and essentially biological process for the production of
plants or animals are excluded from patent protection and on the other hand, microbiological process and the products thereof are declared as eligible for patent protection.

**Patentability under the Patent Act 1970**

Patentability of biotechnological invention in India is governed by the provision of section 2(i)(j), 3 and section 5 of the Patent Act 1970.

The patent can be granted to an invention which is new and useful, and industrially applicable. However section 2(i)(j) of the Patent Act 1970 defines invention as any new and useful,

(I) art, process, method or manner of manufacture

(II) machines, apparatus or other article

(III) substances produced by manufacture, and includes any new and useful improvement of any of them and an alleged invention.

From section 2(i)(j) (I), (II) and (III) it is clear that invention must be a substance produced by manufacture or must result in a machine, apparatus or article. Thus section 2(i)(j) requires that invention should be an article or substance. The Patent Act 1970 does not define the term “manufacture” and “substance”. However, section 2(10) of the Indian Patents & Designs Act 1911 had defined the term “manufacture” as any art process or manner of producing/preparing or making an article and also any article prepared or produced by manufacture. The word “manufacture” has also been defined in the chamber dictionary as “to make originally by hand, now usually by machine and on large scale”. However this definition does not specify that the product so manufactured includes living entities. Therefore while interpreting section 2(i)(j) in consistent with section 18(2)(b), the Controller has assigned the meaning to the word “manufacture” viz., the manufacture must result in a non-living substance.

In Press Metal Corporation Ltd v/s Noshir Edrlgi (AIR 1983 BOM 144) the Hon’ble Bombay High Court has observed that “manufacture in its ordinary parlance generally conveys the ideas of making tangible goods by hand or by machines”. In R v/s wheeler it was observed that “the word manufacture” has been generally understood to denote either as thing made, which is useful for its own sake and vendible as medicine. Therefore, generally held view is that the method or manner of manufacture should result in a non-living substance and not in a living substance. However the word substance as referred in the section 2(i)(j) is used to refer to something produced by manufacture. Although the provisions of the Patent Act 1970 do not indicate about the patentability of living substances but the spirit of the Act is to exclude them.

**Non-patentable matter**

From the point of view of the biotechnological inventions, the provision of section 2(i)(j) must be read with the provision of section 3 of the Patent Act 1970. Under the provision of section 3 certain inventions have been excluded from the scope of patentability. They are

(a) an invention, the primary or intended use of which would be contrary to law or morality or injurious to public health [section 3(b)],

(b) The mere discovery of any new property or a new use for a known substance or mere use of a known process,
unless such known process results in a new product or employs at least one new reactant [section 3(d)],

(c) method of agriculture or horticulture [section 3(h)],

(d) Any process for the medicinal, surgical, curative prophylactic or other treatment of human beings or any process for a similar treatment of animals or plants to render them free of disease or to increase their economic value or that of their product [section 3(i)].

In India, no patent can be granted for inventions in the field of plant propagation by sexual methods under section 3(h). In one of the cases the Controller of Patents & Designs refuses to grant patent for “method for cultivation of an alga” on the ground that the term “agriculture” is not confined to the cultivation of soil only but it relates to the total art of science for production of crops. Similarly it has been also made explicitly clear in section 3(i) that processes for treatment of human beings, animals or plants are not patentable, so also the processes for treatment of animals and plants to increase their economic value. Section 3(d) also makes it clear that mere discovery of new property, new use of known substance and products found in nature are not patentable. Provisions of section 3(b) bar the patentability of inventions which are contrary to law, morality or injurious to public health.

Food, Drug and Medicines

According to the provisions of section 5(a) of the Patent Act 1970 which provides that “In case of inventions, claiming substances intended for use or capable of being used as food, as medicine or drug, no patent shall be granted in respect of claims for the substances themselves. But claims for method or process of manufacture shall be patentable”. It is therefore quite clear that in respect of inventions relating to food, drug and medicines, the patent can be granted only for the process of manufacture of substance and not for the substance per se.

Keeping in view the above provisions under the Patent Act 1970 and also in view of the office instructions of the Controller General of Patents, Designs & Trademarks dated 15 July 1991, viewpoint regarding patentability of biotechnological inventions in India is:

(1) Invention relating to organisms or material per se viz (a) living entities of natural or artificial origin such as animals, plants and microorganisms, biological material such as plasmids, viruses, gene, recombinant DNA, bacteria, fungi, algae and other materials having self replicating properties and parts thereof, (b) naturally occurring substances from living entities, biological materials and also process for their production, are not patentable under the Act.

(2) Inventions relating to process or methods of production of tangible and nonliving substances like enzymes, antibiotics, insulins, hormones, interferons, alcohols etc. by bioconversion or using such microorganisms or by utilizing the above referred biologically active substances as well as chemical substances produced by using genetically engineered organisms or such existing substances made more economically by use of biotechnology and/or microbiology are patentable under the Patent Act 1970.
Provisions under TRIPS

Section V of the TRIPS agreement deals with patents. However, provision relating to patentability of biotechnological inventions are as follows.

(1) **Patentable matter** — Article 27(1) of TRIPS agreement provides that patents shall be available for any invention, whether product or process, in all fields of technology provided that they are new, involve an inventive step and are capable of industrial application. The term inventive step and "capable of industrial application" may be deemed to be synonymous with term "non obvious" and useful respectively. Thus under TRIPS, patent can be granted for any invention in all fields of technology if following requirements are met:

(i) The invention is new

(ii) Involves inventive step (non obvious)

(iii) Is capable of industrial application (useful).

(2) **Exclusion from Patentability** — The provision of article 27(2) has excluded certain inventions from the patentability on the ground to protect order public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment provided that such exclusion is not made merely because the exploitation is prohibited by domestic law. Provisions of Article 27(3) further provide that members may also exclude from patentability (a) diagnostic, therapeutic and surgical methods for the treatment of human or animals, (b) plants and animals and essentially biological processes for the production of plants and animals.

(3) **Exception to exclusion** — Although certain kinds of invention have been excluded from the patentability under Article 27(3) but patenting of microorganism and non-biological and microbiological processes are excepted. Therefore, microorganisms *per se*, process of their production and processes of their use are patentable.

(4) **Protection of plant varieties** — The provisions of TRIPS agreement does not insist upon the members to follow a particular type of system for the protection of plant varieties. However the provision of Article 27(3) (b) provides that members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof. Therefore it is upto the individual member state to provide protection to plant varieties either by patent or by any *sui generis* system.

(5) **Term of the patent** — TRIPS agreement provides a uniform term of protection for 20 years from the date of filing unlike the provision under the Patent Act 1970.

Need of the amendment of the Patent Act 1970

In view of the above stated provisions under TRIPS, there is an obvious and urgent need to amend the Patent Act 1970 in order to make our national law as per with TRIPS. However for doing so India has got time upto 2005.

In order to fulfil the requirement order Article 70 (8) (1) and 70(9) of the TRIPS for the grant of exclusive marketing rights for a
period of five years after obtaining market approval or until a product patent is granted or rejected, provided conditions laid down therein are satisfied, the President of India issued the Patent (Amendment) ordinance 1994 dated 31 December 1994 amending the provision of section 5 of the Patent Act 1970 to facilitate the applicant to file an application for the grant of patent for the product in the manner provided in chapter IV A of said ordinance.

In order to provide a legal status to said ordinance of 1994, the Patent (Amendment) Bill 1995 was brought into Parliament which was duly passed by the Lok Sabha but was not presented in the Rajya Sabha and later on it has been referred to the select committee of Rajya Sabha for their consideration.

Effect of ordinance was that during the year 1995 about 6000 plus applications were filed compared to 3500 to 4000 applications and out of which 2488 applications have been filed in the Patent Office Branch Delhi alone.

Conclusion

It may be concluded from this paper that since the biotechnology based processes and products have now assumed an increasing importance in the global economy, there is a definite need to globally harmonize policies and procedure in respect of protection of Intellectual Property Rights in view of the fact that enterprises engaged in research will make investment only if strong legal protection is available for the result of their research and therefore TRIPS agreement is a step forward in this direction. However it remains to be seen that how the issue of protection of biotechnological inventions by patents is dealt with by the policy makers in our country.