



PROTECTING BIOTECH INVENTIONS: ARE WE READY?

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ISSN 2277-7733**Abstract**

Biotechnology has been used in agriculture, food production and medicine since the dawn of our civilization. Biotechnology is a popular term for the generic technology of the 21st century. With the advancement in science and research, modern biotechnological inventions have brought a revolution in our lives. These inventions are protected under the Patent Law. The World Trade Organization's TRIPS agreement sets down the minimum standards for intellectual property regulation for its member countries. India being one of the members of WTO has fulfilled the TRIPS commitments by amending the patent regime, the latest of which is the amendment of 2005. India has a large pool of scientific talent, world-class information-technology industry, and vibrant pharmaceutical sector. India has a rich human capital, which is the strongest asset for the knowledge based industry. India is also well positioned to emerge as a significant player in the global biotech arena. Though the Indian Patents Law has been very successful in promoting the progress of science but still the patent system is not as stronger as it is in other developed countries. So far as biotechnology is concerned there are no internationally accepted guidelines for the grant of patents and wide range of opinions exists regarding patenting of biotechnological inventions. The protection afforded to these inventions is sensitive and complex and has given rise to several technical and ethical issues. The general aim of this paper is to canvass those issues in the Indian context.

Keywords: *biotechnology, invention, patents*

Human life has touched new horizons with the progress of science and technology and biotechnology is a revolution that has influenced the progress of mankind tremendously. The word bio is taken from Greek word 'bios' which means life. Technology means application of scientific knowledge for practical purposes to get desired results¹. Biotechnology means the scientific knowledge that uses life or living entities like micro-organisms, plants and animals for practical and commercial purposes to get the desired results.

Biotechnology is one of the oldest technologies and is in use for thousands of years. It has been utilized for centuries in traditional production processes. For eg. the production of wine or beer which involves processes using living organisms², Microorganisms are also used to turn milk into cheese and yogurt³, yeast is used in bread to make it rise⁴. All these techniques have been known for a long time and all of these can be considered biotechnology because it utilizes living organisms. Likewise, the selective breeding of plants and animals has an equally long history. What may be described as modern biotechnology is distinct from classical fermentation technology. Modern biotechnology is only about 50 years old, and in the last decades it has witnessed tremendous developments⁵ like rDNA techniques, hybridoma technology, Polymerase Chain Reaction and cloning methods. Further advances in biotechnology are interdisciplinary techniques like information technology and nano-technology etc. which is considered as the foundation of modern biotechnology⁶.

Today biotechnology has applications in four major industrial areas, health care (medical and cosmetics), crop production and agriculture, non food (industrial) uses of crops and other products (e.g. biodegradable plastics, vegetable oil, bio fuels), environmental uses (bioremediation).

As in other fields of technology, there is also a need for legal protection in respect of biotechnological inventions. Such inventions are creations of the human mind just as much as other inventions, and are generally the result of substantial research, inventive effort and investment in sophisticated laboratories. Typically, enterprises engaged in research only make investments if legal protection is available for the results of their research. As with other inventions, there is an obvious need for the protection of biotechnological inventions, not only in the interest of inventors and their employers, but also in the public interest in order to promote technological progress. A biotechnological invention is dealt with patent laws under intellectual property rights.

Indian Law on Patents

The Patents Act, 1970, is a landmark in the industrial development of India. The basic philosophy of the Act is that patents are granted to encourage inventions and to secure that these inventions are worked on a commercial scale without undue delay and not merely to enable patentee to enjoy a monopoly of the patented article.

The Agreement on Trade Related Aspects of Intellectual Property Rights popularly known as TRIPS is an international agreement administered by the World Trade

Organization (WTO) that sets down minimum standards for many forms of intellectual property regulation as applied to nationals of other WTO Members. It was negotiated in the year 1994. The TRIPS agreement introduced intellectual property law into the international trading system for the first time and remains the most comprehensive international agreement on intellectual property till date. TRIPS agreement under Article 27.1 provides that patents be available in all fields of technology, without discrimination, provided that they are new, involve an inventive step and are capable of industrial application. Article 27.2 enables a Member to exclude from patentability inventions whose commercial exploitation may be contrary to public order or morality. Further, Article 27.3 also allows Members to exclude from patentability certain subject matter, such as plants and animals.

India being a signatory to WTO's TRIPS agreement was put under the contractual obligation to amend its Patents Act in compliance with the provisions of TRIPS. Accordingly the Indian Patent Act, 1970 was amended in 1999, 2002 and 2005 to meet the requirements of TRIPS.

Issues in grant of patent in India

Indian biotechnology industry has lots of strengths like good human resource, academic resource, clinical capability, vast bio-diversity, large domestic market, large export potential and most importantly low cost research base for international companies in comparison with other countries but still the Patent law needs to be clearer on the criteria for the patentability of biotechnological inventions. Robust intellectual property rights framework is the need of the any nation⁷. Though India is already a member to various international treaties and agreements but still significant improvement remains in the areas of implementation and enforcement of patent laws.

Some of the issues concerning biotech patents are discussed as under:

Life forms: Discovery v. Invention

Discovery means merely making available what already exists in nature. A substance freely occurring in nature, if merely found or discovered, is not patentable. However, if the substance found in nature has first been isolated from its surroundings and a process for obtaining it, is developed, that process is considered invention and hence patentable⁸. Biotechnology invention also includes inventions relating to an organism or material such as living entities of natural or artificial origin (animals, plants, and microorganisms), biological material (plasmids, viruses and replicas, and parts of organs, tissues, cells, and organelles), and naturally occurring substances from living entities, biological material and parts⁹.

The first area of concern relates to the legal standards in respect of the scope of patent protection for inventions in the field of biotechnology. Since Intellectual Property

Right protection is granted only for invention and not for discoveries, in case of biotechnology innovations, it is difficult to say whether the new life form in the form of gene, DNA, cell, microorganism etc. is a scientific discovery or a technological invention. Hence a most critical problem faced by the biotechnological inventions is the interpretation as to what constitutes an invention in contrast to a discovery¹⁰.

Secondly, several Non-Governmental Organizations argue that naturally occurring organisms are God's gift and therefore are common property of the mankind and therefore cannot be appropriated by any person(s) or organizations or entities by just modifying it or tinkering with it. In case of modern biotechnology, these objectors do not see much innovation being done, and therefore argue that any life form innovations must not be granted patent.

Thirdly, there are several ethical issues related to patenting of life forms, the most important being extent of private ownership that could be extended to life forms. It is argued that that nature has provided equal rights to all living beings. Human beings do not have rights over other living beings and therefore rights of none of the human beings are higher than each other¹¹. Hence human beings cannot take other living beings for granted and they cannot play with dignity and integrity of such living beings by manipulating them.

In spite of various issues involved in patenting biotechnology, it has brought enormous benefits to the society. The application of biotechnological inventions has extended to biomedical technologies like recombinant drugs, recombinant diagnostic kits and vaccines; to the agricultural sector in producing GM crops which are pest resistant and have high nutritional qualities; marine biotechnology which includes fish farming; environmental biotechnology including treatment of air pollution; forestry for tissue culture and production of wood for paper manufacture. Hence the benefits of biotechnology cannot be sidelined in the modern world as it is capable to cater the needs of the society.

Deposition requirements

Whether the claimed invention is a new microorganism itself or a new product obtained from it, the patent will be invalid unless it gives a disclosure of the invention that is sufficient to enable it to be reproduced. It is practically impossible to give a written description of a strain of a microorganism. In order to meet this problem the Budapest Treaty of 1977, which came into force in 1980 establishes a list of International Depository Authorities and provides that a single deposit made at any of these depositories will suffice for all signatory states. A serious problem arises is that most countries now have early publication of patent applications (18 months from the priority date) and consider that as a part of publication



the deposited strain must be made available from this time. This means that the applicant has to make his invention available to public, including his competitors, before there is any assurance that he will actually obtain patent protection. The traditional concept of patent protection as exchange for disclosure has thereby been distorted so as to require, before any protection exists. This has been aptly described as a 'pocket factory handed over to the imitator on a silver plate'.¹²

Liberal stand taken by other countries

Two of the Sections 3(c) and 3(j) are important in the context of patentability of biotechnological inventions. Section 3 (c) states that "The mere discovery of a scientific principle or the formulation of an abstract theory or discovery of any living thing or nonliving substances occurring in nature will not be considered as patentable invention". This provision of non-patentability is common to patent laws of other countries. The Clause 3(j) states that "Plants and animals in whole or any part thereof other than microorganisms including seeds, varieties and species and essential biological processes for production or propagation of plants and animals as non-patentable invention". This provision differs from the patent laws of countries like the US, the European Union, and Japan, who follow liberal patent standards and where patents are also granted to genetically modified animals and plant varieties¹³.

Small and marginal farmers' rights

Article 27 (3)(b) of TRIPs agreement allows members to exclude from patent protection, plants and animals other than micro-organisms; and biological processes for the production of plants or animals other than microbiological processes. TRIPs provide option to member states protecting new plant variety by means of patent or sui generis system or both. India opted for sui generis protection and has legislated "Protection of Plant Varieties and Farmers Right Act, 2000" that enables the farmer to save, use, sow, re-sow, exchange, or share the seeds of protected variety, besides offering protection on farmers' variety, extant variety and essentially derived variety. Whereas plant variety protection could boost research in the area of plant biotechnology by both public and private bodies, it could also result in higher prices for seeds, thus naturally excluding the small and marginal farmers from accessing such new technologies¹⁴. Farmers accustomed to harvesting and replanting their seeds are not willing to pay for GM seeds year after year. These debates draw attention to the controversial TRIPs Article 27.3(b), which exempts certain life forms from patentability but requires countries to establish some form of protection for plant varieties.

Apart from the above issue there have been claims of genetically-modified seeds being responsible for the farmer suicides¹⁵ as the farmers using genetically-modified

seeds led to rising debts which forced them to commit suicide when they do not get the returns after the seeds are cultivated. The decade of experience has shown that though biotechnology has benefited the seed industry but not the poorest of farmers which has resulted in agrarian distress and farmer suicides¹⁶.

Health and environment issues

The principal cause of the debate surrounding products of biotechnology is the uncertainty of the long-term health and environmental effects of genetically modified living materials. Though many scientists believe genetically-modified foods to be safe, a small but influential group of researchers believe uncertainty about their effects on human health. Transfer of genes from genetically-modified to wild plants could create health problems in humans, anti-biotic resistance in plants and associated insects, long-term damage to ecosystems, loss of biodiversity and lack of consumer choice¹⁷.

Other relevant issues, such as the conservation and preservation of the environment (including the protection of biodiversity) and moral and ethical dimensions of the protection and commercialization of biotechnological inventions have been discussed in many fora. Advocates of sustainable development also wary of the long term effects that genetically-modified crops could exert on the environment.

Genetically-Modified Food and Hunger

Producers of genetically-modified crops argue that biotechnology could be the world's cure for hunger. They cite that the technology has the ability to produce high yields, resist natural disasters such as drought and certain viruses and be enriched with vital nutrients that starving people are likely to lack¹⁸. However, aid agencies and anti-GM countries argue that in many countries where hunger is a major problem, adequate amounts of food to feed their population has to be produced. Hunger, they argue, is not only a function of agricultural yield; it is also a function of mismanaged government and a series of other factors, which technology cannot resolve.

Defenders of biotechnology often argue that genetic manipulation holds the key to eliminating hunger and suffering across the world. One commonly cited example is 'Golden rice' which scientists have engineered to produce extra Vitamin A. The rice has been hailed as a godsend for malnourished people in the developing world because Vitamin A helps prevent blindness. Critics take two different stances on these wonder-foods. Some refer to recent studies and statements by doctors that Golden rice is not a sufficient source of Vitamin A. Specifically, people with diarrheal diseases are incapable of absorbing Vitamin A from the rice, and thus people in developing countries who commonly suffer from diarrheal disease and Vitamin A deficiency remain afflicted by both. Other critics reply that 'Franken foods' are the wrong answer to

the problems of hunger and malnutrition, which they claim are the outcomes of distributional problems. Instead of posing a viable long-term solution, genetically-modified foods distract from and exacerbate the real issues involved¹⁹.

Criteria for patenting

In addition to the question of patentable subject matter, the patentability requirements, i.e. novelty, industrial applicability (utility), non-obviousness and disclosure requirements has been subject to an intense debate²⁰. The consideration of industrial application is an obstacle for securing patents for inventions in biotechnology. Standards of novelty and non-obviousness are difficult to set for living organisms. Most developed countries now recognize that novelty is met if the claimed biotechnological product or process does not exist in the prior art. Sufficiency of disclosure is met for microorganisms by depositing microorganisms in any of the internationally recognized depository under the Budapest Treaty²¹. Hence an inventor apart from proving that his invention is a subject matter of patent has to comply with the above requirements which make it difficult for him to get the grant of patent.

Inventive Step

With the rapid progress in the field of biotechnology, something called as a 'revolutionary practice' quickly turns into 'standard practice'. The state of the art changes so dramatically within the time during which a patent application is pending and this makes it difficult to judge the invention in the light of what was the state of art at the filing date²².

Problem of Bio piracy

Farmers and indigenous peoples in developing countries such as India are facing serious problems as plants that they developed and conserved are being 'appropriated' by private entities leading to bio piracy and exploitation of traditional knowledge claiming the exclusive right to produce and sell many 'modified' plants and animals. This is a great matter of concern today that knowledge, innovation and efforts of these communities are not acknowledged when the legal 'intellectual property rights' systems grant patents on genetic and biological materials and on living organisms to private corporations.

Moreover due to difficulties in obtaining patents in India, CSIR in 2000, found that almost 80 per cent of the 4,896 references to individual plant based medicinal patents in the United States Patents Office that year related to just seven medicinal plants of Indian origin. Three years later, there were almost 15,000 patents on such medicines spread over the United States, UK and other registers of patent offices. In 2005 this number had grown to 35,000, which clearly demonstrates the interest of developed world in the knowledge of the developing

countries²³. Whilst the corporations stand to make huge revenues from this process, the local communities are unrewarded and they in fact face the threat in future of having to buy the products of these companies at high prices. Hence such system of IPR only benefits the private industries or multi-national corporations of industrially developed countries at the expense of the developing countries. There is need to define guidelines and policies for the implementation of IPR in India so that the people like farmers get recognition for their efforts and contributions prevent bio-piracy. World Intellectual Property Organization is now developing guidelines to protect traditional and indigenous knowledge systems²⁴.

Conclusion

India is a country where ethics and morality are respected and adhered to at par with law. Indian tradition is well known for worshipping animals and plants. For an Indian, patenting plant, animals and other living beings would be like patenting and owing God. The Patents Act addresses ethics in patenting invention in general by saying that inventions which are against ethical and moral standards are not patentable. The amended Patents Act states that any invention, the exploitation of which is against public order and morality and that may cause serious prejudice to the health of human beings, animals or to the environments cannot be patented.

Biotech industry is one of the fastest growing industries in the world, including in India. India is a storehouse of biological resources and is one of the world's richest biodiversity countries. In recent years, there has been a rise in the investment in the biotech oriented industries²⁵. The importance of India in the field of Biotechnology is manifold. In addition to generating trained manpower and a knowledge base, India is proving to be an ideal setting for manufacturing activities and high-level biotechnology research programmes. With the initiatives taken by the government, Indian Biotechnology is poised for a tremendous growth.

Strong intellectual property rights in biotechnology are of critical importance for the continuous growth of the biotechnology industry. In either case, India companies, inventors and investors venturing into the biotech sector must be well informed and well aware of India laws, as well as the laws of other countries as they seek to join the biotechnology headlines. Also India is rich in traditional knowledge associated with biological resources.

In light of the increasing research in human genetics, the Indian Council for Medical Research issued guidelines²⁶ to evaluate the ethics involved in human genetics. As the effect of ethical issues raised by research in human genetics is acute, these guidelines admit that ethical considerations in human genetic research are desirous compared to research in plants and animals. The



guidelines intend to guarantee human rights and dignity vis-a-vis genetic research where human beings, human tissues, cells and genetic material are being used as subjects. The guidelines acknowledge International Conventions on human rights and fundamental freedoms. Biotechnology has faced problems in achieving equal protection in the patent system in different countries. Each and every application on biotechnology patent has to be rethought and interpreted anew in biotechnology. Due to this reason, many leading patent law decisions of the last decade have resulted from biotech cases.

The increase in research activities in the field of biotechnology has resulted in the optimum utilization of biotech resources, flow of investments and increased number of patents in the field of biopharmaceuticals. The evolutionary trends in patenting of biotech inventions are creating complexities and are becoming challenging tasks for the authorities in granting patents.

Today, biotechnological inventions face many critical issues, but still biotechnology has invented countless number of non-natural living beings or inventions involving life by manipulation of existing living beings, which have served and are serving the society. With its potential to manipulate living beings in a way as would benefit the society, biotechnology is promising to be capable of catering to the needs of the society.

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