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Do We Need Patent Protection to Biotechnology Inventions?

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Abstract- The growing research and development activities in the field of biotechnology are a new addition to intellectual property regime. Serious efforts are being made to increase the number of inventions and filling of applications for patents. The inventions, which involve more of living organisms, became controversial issues. The standard tests of patent law are obstacles for grant of patents to the biotech inventions. Non-grant of patents encourages uncontrolled piracy of new inventions and the original owners suffer economic losses because of low returns on their huge investments in the research. TRIP, agreement seeks to enforce patent laws around the world including biotechnological inventions. In India, the existing patent laws were amended to comply with TRIPs agreement. But do we really need patent protection to the genetically modified animals is the question of the day.

Index Terms- Biotechnology, TRIPs, Patent protection, IPR Laws

I. INTRODUCTION

For thousands of years human beings have exploited biological resources for medical, agricultural and other purposes. Modern biotechnology is only the latest fashion by which man is able to use his natural environment to feed, cure and house him. In the last decade the application of modern biotechnology for agricultural, ecological and medical purposes has sparked great hoes for the extent to which man can explore and exploit biological resources for his wellbeing. Biotech inventions are gaining popularity as they help identify the root cause of chronic diseases and suggest remedies. Biotechnology is a new area of science that compounds life sciences of chemical sciences. Genes in plants, providing for certain special features, would be isolated and put together into one plant with the help of biotechnology. Through the process of biotech by manipulation of genes new variety of animals can be invented. These new variety of animals can be used for different purposes such as production of medicines, for experimental for testing of medicines and treating methods.

Earlier patents were not granted to genetically modified organisms and other products derived from living systems. With the advancement of the technology, protection of biotechnological invention also started. But protection to the inventions, which involve more of living organisms, became more complex and controversial. The standard tests of patent law are obstacles for grant of patents to the biotech inventions. Non-grant of patents encourages uncontrolled piracy of new inventions and the original owners suffer economic losses because of low returns on their huge investments in the research. Now TRIPs, agreement seeks to enforce US style patent laws around the world. This agreement covers everything from pharmaceuticals to information technology software and human gene sequences. At this juncture, the author points out impact of extension of patent protection to genetically modified organisms in India.

II. WHAT IS BIOTECHNOLOGY?

The word 'biotechnology' was actually coined early in the 20th century by an agricultural engineer from Hungary, named Karl Earky, who explained it in such a way that the technology which include all such work by which the products are produced from raw materials with the aid of living organisms. Subsequently, over the period, the definition of biotechnology acquired a confusing status due to various interpretations[1].

Classical biotechnology may be defined loosely as the production of usual products by living organisms, and as such it has been with us for a long time. The first official broad definition given by the US Office of Technology Assessment states, "biotechnology includes any technique that uses living organisms(or parts of organisms) to make or modify products, to improve plant or animals or to develop microorganisms for specific use"[2].

Biotechnology can be traced back to various stages of its development. the first generation of biotechnology can be based on the traditional knowledge in various tribes like preparing fermented foods, medical distillates etc. second generation of biotechnology may be considered when the utilisation of micro-organisms started on industrial scale during the Pasteur era which involved mass production of alcohol, fermentation of antibiotics, development of classical vaccines like for cholera, typhoid, yellow fever etc.

The third generation of biotechnology, as distinct from classical fermentation technology, began in 1970s with the two basic techniques of recombinant DNA technology and Hybridoma technology. In the first of these, also referred to as gene splicing or genetic engineering, genetic material from an external source is inserted into a cell in such a way that it causes the production of a desired protein by the cell; in the second,

[1] Dr. K. K. Tripathi, *Biotechnology and IPR Regime: In the Context of India and Developing Countries,* "Biotech Patent Law",1st Ed.(the Icfai University Press,2007) p.,187

[2] Philip W. Grubb, *Patents for Chemical, Pharmaceuticals and Biotechnology*, 4th Ed,(New Delhi: Oxford University Press) 2006. P. 245-246

different types of immense all are fused together to form a hybrid cell line producing monoclonal antibodies.[3]

The fourth generation of biotechnology would see further advances where interdisciplinary techniques like information technology and nano-technology would get involved in further advancement of this discipline, especially utilising the bioinformatics which is the foundation of modern biotechnology. Bioinformatics can be broadly defined as the use of computers to handle biological information.

III. Patents and Biotechnology

The ownership and exploitation of intellectual property rights are the key factors in determining the success of any technological invention introduced in the market that provide the means for technological progress to continue or to be made thereby support the competitiveness of the industry of the country. The regulatory mechanisms in IPR have their own problems in the coming scenario of emerging technologies especially in biotechnology.

Biotechnology is the result of efforts of intellect, the application of human intelligence and knowledge to the biological processes. These human intellectual efforts deserve protection. The new plans, animal varieties, new methods of treatments, new crops producing food articles as such are the inventions of biotechnology. These inventions have to be protected for obtaining the fruits of biotechnology.

Biotechnology has based a whole new industry and patent protection for biotechnological inventions is of immense commercial importance. But patent law and practice have had serious difficulties in keeping up with the rapid scientific progress in this field and issues such as inventions steps, sufficiency of disclosure and permissible breadth of claims have proud troublesome. There has been much litigation of biotech plants and courts have found it difficult in such a rapidly moving field to determine what the general knowledge of the skilled person was at the time invention was made. A procedure to find and clone a specific gene and to express it in a suitable has may have been a breakthrough at the time when it was first done and purely routine work, not many years later. There is also the problem of opposition by special interest groups against anything to do with genetic engineering and particularly against the existence of patents in this area[4].

IV. Patenting of Micro-organisms and Cells

Patents on biotechnological processes date from the early days of the United States. Louis

Pasteur received a patent for a process of fermenting beer. Acetic acid fermentation and other food patents date from the early 1800s, while therapeutic patents in biotechnology were issued as early as 1895. The development of recombinant DNA technology (rDNA), i.e., the controlled joining of DNA from different organisms has resulted in greatly increased understanding of the genetic and molecular basis of life. Following the first successful directed insertion of recombinant DNA into a host micro-organism in 1973, scientific researchers began to recognize the potential for directing the cellular machinery to develop new and improved products and processes in a wide variety of industrial sectors. Many of these products were micro-organisms (microscopic living entities) or cells (the smallest component of life capable of carrying on all essential life processes). With the development of recombinant DNA technology, the potential of patenting the living organism resulting from the technology arose.

Prior to 1980, patents were not granted for such inventions, deeming them to be "products of nature" and not statutory subject matter. Although patent applications were rejected if directed to living organisms per se, patent protection was granted for many compositions containing living things (e.g., sterility test devices containing living microbial spores, food yeast compositions, vaccines containing attenuated bacteria, milky spore insecticides, and various dairy products). In the absence of congressional action, it took a catalytic court decision to clarify the issue of patentability of living subject matter.

The Supreme Court's single foray into biotechnology occurred in 1980 with its ruling in the patent law case *of Diamond v. Chakrabarty*[5]. Chakrabarty had developed a genetically modified bacterium capable of breaking down multiple components of crude oil. Because this property was not possessed by any naturally occurring bacteria, Chakrabarty invention was thought to have significant value for cleaning up oil spills. Chakrabarty's claims to the bacteria were rejected on two grounds:

1. Micro-organisms are "products of nature;" and
2. As living things, micro-organisms are not patentable subject matter.

Following two levels of appeals, the case was heard by the U.S. Supreme Court, which in a 5-4 ruling, held that a live, human-made microorganism is patentable subject matter. The *Chakrabarty* decision provided great economic stimulus to patenting of micro-organisms and cells, which in turn provided stimulus to the growth of the biotechnology industry in the 1980s. [6]

V. Patenting of Animals

The first animal patent was issued in April 1988 to Harvard University for mammals genetically engineered to contain a cancer-causing gene (U.S. 4,736,866). The patented mouse was genetically engineered to be unusually susceptible to cancer, thus facilitating the testing of carcinogens and of cancer therapies. Specifically, the patent covers "a transgenic non-human eukaryotic animal (preferably a rodent such as a mouse) whose germ cells and somatic cells contain an activated onco gene sequence introduced into the animal which increases the probability of the development of neoplasm (particularly malignant tumors) in the animal."

[3] *http://www.iprcommission.org*

[4] C.B.Raju, *Intellectual Property Rights*, 1st Ed., (New Delhi: Serials Publications), 2006.

[5] *447* U.S. 303 (1980).

[6] http://www.fas.org/ota/reports/8924.pdf

The claim in this patent was a transgenic non-human mammal all of whose germ cells and somatic cells contain a recombinant activalid Onco gene sequence introduced into the said mammal or an ancestor of the said animal at an embryonic stage. The rat race continued and at least 16 patents have been awarded on inventions related to transgenic mice as models exhibiting specific pathologies, such as ulcers, photo Parkinson's syndrome, inflammation, sickle cell anaemia, Alzheimer's disease, HIV infection, Cutnieous melanoma, leukaemia, thrombocytopenia etc[7].

VI. Transgenic Animals and Patenting

Most potentially patentable animals are likely to be transgenic animals produced via recombinant DNA techniques or genetic engineering. Transgenic animals are those, whose DNA or hereditary material has been augmented by adding DNA from a source other than parental germplasm, usually from different animals or from humans. Laboratories around the world are conducting research that involves inserting genes from vertebrates (including humans, mammals, or other higher organisms) into bacteria, yeast, insect viruses, or mammalian cells in culture. A variety of techniques, most developed from early bacterial research, can now be used to insert genes from one animal into another. These techniques are known by a number of exotic names: microinjection, cell fusion, electroporation, retroviral transformation, and others[8].

VII. TRIPs and Biotechnology Patenting

Genetic resources have in the past been declared "a common heritage of mankind to be preserved and to be freely available to all, for use for the benefit of present and future generations". This philosophy has done well to the country in general and to the society in particular, in the long run by enabling access to such creations and knowledge to all without discrimination. But in recent times the industrial countries are busy in the protection and privatization of inventions in the area of living objects or substances such as patenting of micro-organisms and animals. Such steps were generally not accepted by the developing countries including India.

However, TRIPs agreement encourages protection of knowledge and it seeks to enforce US style patent laws around the world. This agreement covers everything from pharmaceuticals to information technology software and human gene sequences, and is emerging as a major issue dividing North and South. TRIPs agreement forces all countries to accept a medley of new biotech patents covering genes, cell lines, organisms and living processes that turn life into commodities. Governments all over the world have been persuaded into accepting these 'patents on life' before anyone understood the scientific and ethical implications.

The patenting of life-forms and living processes is covered under Article 27.3(b) of TRIPs. The TRIPS Article 27.3(b) is designed to allow the broadest categories of patents from genetic engineering and other new biotechnologies. The patenting of life-forms and living processes is covered under Article 27.3(b) of TRIPs. This scientific briefing explains why such patents should be revoked and banned on the following grounds:

- All involve biological processes not under the direct control of the scientist. They cannot be regarded as inventions, but expropriations from life.
- The hit or miss technologies do not qualify as 'inventions', and are inherently hazardous to health and biodiversity.
- There is no scientific basis to support the patenting of genes[9], genomes[10], cells and microorganisms[11], which are discoveries at best.
- Many patents are unethical; they destroy livelihoods, contravene basic human rights, create unnecessary suffering in animals or are otherwise contrary to public order and morality.
- Many patents involve acts of plagiarism of indigenous knowledge and bio-piracy of plants (and animals) bred and used by local communities for millennia[12].

In India, as it is mandatory for all the member countries of the WTO to adopt the agreements of WTO, the Ministry of Science and Technology has issued guidelines "Instructions for Technology transfer and Intellectual Property Rights", which would help in enhancing the motivation of the scientists, research institutions and universities in various research and development projects funded by various departments of the Ministry of Science and Technology. The salient features of these guidelines are as follows:

a) Ownership of Intellectual Property: the institution shall be encouraged to seek protection of IPR rights in respect of the results of R&D. they may retain the ownership of such IPRs. Institution means any technical, scientific and academic establishment where the research is carried through funding by central or state governments.
b) Transfer of Technology: the institutions would take necessary steps to commercially exploit patents on exclusive or non-exclusive basis.

[7] http://www.slwk.com/SLWK/web/company/papers/paper14.html

[8] Arnold,Beth E. and Eve Ohgeilski-Zei, "Patenting Genes and Genetic Reasearch Tools: Good or Bad for Innovation", Annual Review of Genomics and Human Genetics(2002), P. 416.

[9] Gene is a stretch of genetic material (DNA or RNA) with a defined function in the organism or cell. It usually codes for a protein.

[10] A genome is the totality of all the genetic material (deoxyribonucleic acid or DNA) in an organism, which is organised in a precise, though by no means fixed or constant way. In the case of viruses, most of them will have ribonucleic acid or RNA as the genetic material.

[11] A micro-organism is an organism that can be seen only under a microscope, usually, an ordinary light microscope. It includes bacteria, mycoplasm, yeasts, single-celled algae and protozoa.

[12] Cooper, I. P., *Biotechnology and the Law, (New* York, NY: Clark Boardman, 1985).

c) Royalty to inventors: owner institutions are permitted to retain the benefits and earnings generated out of the IPR. Institutions may determine the share of the inventors and other associated persons from such earnings. However such sharing is limited to one third of such earnings.
d) Norms for the private industry: IPR generated through joint research by institutions and industrial concerns through joint research efforts can be owned jointly by them on mutually agreed terms through a written agreement. The institution or industrial concern may transfer the technology to the third party for commercialisation on exclusive or non-exclusive basis.
e) Patent Facilitating Fund: the owner institution shall set apart not less than 25% of the revenues generated from IPR to create a patent facilitating fund. The fund shall be utilised by the owner for updating the inventions, filing applications for new patents and protecting the IPR against infringement and for building the competency in the area of IPR and related issues.
f) Information: the institution shall submit the information relating to the details of the patents obtained, the benefits and earnings arising out of the IPR and the turnover of the products periodically to the Department/ministry, which has provided the funds[13].

VIII. Do We Need Biotechnology Patents?

The industries that utilise biotechnology are convinced that intellectual property protection should be obtainable for the inventions that stem from research and which have commercial potential. Biotechnology research workers in academic institutions increasingly share this view because of their need for research funding which is in part conditional on patentability.

But many people are not in favour of biotechnology patents. For many such groups "patenting life" is considered unethical in principle. The opposition extends also to possible structural change in the agricultural industry which might stem from biotechnology and especially from the acquisition by the larger corporations of legal rights on the advances that are being made.

A legally permissible ground of objection is that genes are naturally occurring entities and that the methods for transferring them to plants or animals are well-known and straightforward. This is a challenge to the inventiveness content of the particular patent at issue; it is an argument that industrial competitors will sometimes use against each other's patents but so far it has not achieved a high success rate. The argument also lies at the heart of the moral objections many with religious beliefs have to patenting genes. They regard claims of invention, instead of discovery, tantamount to claiming to be God.

Some feel that patenting living things change the relationship between humanity and the rest of nature. This is particularly sensitive as regards animals, where patents are seen as conferring "ownership", thereby undermining the animal's right to independence of being and relegating it to the status of a mere object. However, plants and animals are owned by the farmers who produce them and use them as agricultural commodities. All such owners, whether of patented or unpatented organisms, are bound to respect animal welfare legislation.

The objection to animal suffering may also apply to the genetic modification of farm animals. One early experiment to insert a growth hormone gene into a pig in order to increase growth rate succeeded but caused severe unforeseen side effects including arthritis. Animal welfare groups argue that patents will encourage more research on animal genetic modification, which they oppose on grounds of possible suffering and of principle. Intended to prevent undue suffering, legislation requires the granting of animal experimentation licenses and full disclosure of the experimentation.

The patentability of genes and other nucleic acid sequences is justified on the ground that they have been subject to a microbiological or non-biological process, i.e, gene sequencing, which is itself a standard process patentable and patented under existing patent laws for invention. So, the actual patented entity is the nucleic acid sequence itself and its putative function. However, the DNA or RNA sequence is subject to change by mutation, deletion, insertion and rearrangement.

The patenting of genomes raises the question of the function of the genomes. Again, the isolated genome can do nothing by itself, while its "function" in the organism cannot be considered separately from the totality of the organism.

IX. Conclusion

It can be concluded that, genetically modified microorganisms and even higher level animals like mammals can be patentable under the Patent laws of several Countries. The WTO, under TRIPs Agreement seeks to enforce US type patents in all the member countries. The concept of patenting the biotechnological inventions has been opposed by many groups on moral grounds. The author opines that, all biotech patents should be rejected on the following grounds:

- All involve biological processes not under the direct control of the scientist. They cannot be regarded as inventions, but expropriations from life.
- The 'hit or miss technologies' associated with many of the 'inventions' are inherently hazardous to health and biodiversity.
- There is no scientific basis to support the patenting of genes, genomes, cells and microorganisms, which are discoveries at best.
- Many patents are unethical; they destroy livelihoods, contravene basic human rights, create unnecessary suffering in animals or are otherwise contrary to public order and morality.

[13] Tripathi K. K., *Biotechnology: Government of India Initiatives*, Saketlnd Digest,Feb.2002.pp.49-53.

- Many patents involve acts of plagiarism of indigenous knowledge and bio-piracy of plants (and animals) bred and used by local communities for millennia.

REFERENCES

[1] Tripathi K. K., *Biotechnology and IPR Regime: In the Context of India and Developing Countries*, "Biotech Patent Law",1st Ed.(the Icfai University Press,2007) p.,187

[2] Philip W. Grubb, *Patents for Chemical, Pharmaceuticals and Biotechnology*, 4th Ed,(New Delhi: Oxford University Press) 2006. P. 245-246

[3] C.B.Raju, *Intellectual Property Rights*, 1st Ed., (New Delhi: Serials Publications), 2006.

[4] Arnold,Beth E. and Eve Ohgeilski-Zei, "Patenting Genes and Genetic Reasearch Tools: Good or Bad for Innovation", Annual Review of Genomics and Human Genetics(2002), P. 416.

[5] Cooper, I. P., *Biotechnology and the Law, (New* York, NY: Clark Boardman, 1985).

[6] Tripathi K. K., *Biotechnology: Government of India Initiatives*, Saketlnd Digest,Feb.2002.pp.49-53.

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