



TO DETERMINE THE SIGNIFICANCE OF PATENT LAWS AGAINST PLAGIARISM OF BIOTECHNOLOGICAL INVENTIONS

Mahmood Khan Yousufi

Department of Microbiology, Jawaharlal Nehru College, Shyamla Hills, Bhopal, Madhya Pradesh, India. 462002

*Corresponding author email: mkhanyousufi@gmail.com

ABSTRACT

The modern era has witnessed the exponential development activities in the field of biotechnology. This has added an increase in the number of inventions that are being filed for granting patents. The inventions that incorporate biological inventions are more controversial in granting patents. The restrictions in the granting patents results in plagiarism of biotechnological inventions. The greed of economic profits persuades plagiarism of original inventions. In India and abroad patents laws have been laid down to restrict plagiarism of biotechnological inventions. The TRIPS agreement is an international patent law that is widely accepted throughout the world and many countries have formulated their national patents laws in accordance to this agreement. The present study was undertaken to determine the significance of patent laws against plagiarism of biotechnological inventions.

KEY WORDS: Biotechnological inventions, commercialization, patent laws, plagiarism, Trips.

INTRODUCTION

The modern era biotechnology is quite effective in converting products available from the natural resources into useful products (Frazzetto, 2003). These products can further be used for human welfare. In fact for hundreds of years human beings have been using biological resources for the purpose of agriculture, medicines etc (Jianming, 1987). In the recent years, the use of advanced biotechnology in biological resources for the purposes of agriculture, medicine has sparked patent war among the biotechnological industries. This has led to the theft of knowledge of inventions. The biotechnological inventions play an important role in diagnosis of chronic diseases, curing of chronic diseases and thus supported as a remedy for human welfare. The biotechnology is the area of science that incorporates various constituents of life sciences and chemical sciences. The advanced plant biotechnology deals with incorporation of genes. This method of manipulation of genes can be used for development of desired new variety of plants and animals (Srinivasalu and Raju, 2008). The new developed plants can further be used in agriculture for better crop production and that the animals can be used for experimental purposes for testing medicines and treatment of diseases.

In the past patenting the products obtained from biological resources was not considered. It was thought that the products of biological resources are the products of nature and not inventions. The development in the field of biotechnology indulged various measures to protect the biotechnological inventions at the global level. However, the biotechnological inventions that deal with living organisms are very complex and controversial. To determine the standard guidelines for granting patents of biotechnological inventions is a challenge. The non

granting of patents caused plagiarism of biotechnological inventions. This led to the economic loss to the original inventors who invested a huge investment for their product. The launch of TRIPS agreement enforced patents laws on biotechnological inventions throughout the world. This agreement included technology related to pharmacy, bioinformatics and even human gene sequences. It was because of TRIPS that genetically modified organism were granted patent at international level and national level. The TRIPS laws are widely accepted globally (Correa and Yusuf, 2008).

Understanding Biotechnology

In the 20th century the term biotechnology was coined in Hungary by Karl Ereky, who described it as the technology by which products are produced by using raw material obtained from biological resources and living organisms (Verma *et al.*, 2011). However, the interpretation of biotechnology by different researchers differently eluded confusion in defining biotechnology (Tripathi, 2007). The historical definitions define biotechnology as production of useful products by living organisms. The official definition for biotechnology was given by the USOTA (United States office of Technology Assessment) which states that 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 purpose (Committee on Japan, national research council, 1992).

The development in the field of biotechnology can be classified into various stages. The classical stage of development of biotechnology deals with productions of biological products by using traditional knowledge of indigenous states (Reddi and Laxmikumaran, 2015). In

this stage various fermented foods and biochemical products from plants are produced. There after the transition stage of development of biotechnology started. This stage involved use of microorganisms at industrial scale for production of biological products, like alcohol, antibiotics, vaccines etc (Patnaik *et al.*, 2012). After this, modern stage of development of biotechnology was initiated. This stage started in the decade of 1970s. In this stage two important techniques, recombinant DNA technology and Hybridoma technology (monoclonal antibodies) were introduced (Springer, 1985). This stage also included the techniques of genetic engineering and gene sequencing. The latest advanced stage of development of biotechnology involves techniques like bioinformatics and nano technology. The bioinformatics deals with the use of computer in configuring biological information (Ramsden, 2004). Nanotechnology ("nano tech") is manipulation of matter on an atomic, molecular, and supramolecular scale (Mansoori, 2005).

Scenario of Patenting in Biotechnology

The two factors of intellectual property rights, ownership and exploitation are the key to develop biotechnological inventions. These two factors also contribute to competition for latest research and development in the field of biotechnology. However new regulatory patent laws are required to deal with the latest emerging biotechnological inventions. Biotechnology has emerged due to the effective efforts of intellectuals who incorporate the human skills and knowledge to develop biological processes. The human skills and knowledge used in biotechnological techniques are required to be protected (Bull *et al.*, 1982). The biotechnological inventions include development of new plant varieties, new animal varieties, new treatment methods etc. The biotechnological inventions must definitely exhibit that they have industrial application that are useful for human welfare. The patenting of biotechnological inventions is of immense commercial importance. But there are various hindrances in this regards. The complications arise due to plagiarism of biotechnological inventions. The patent authorities have found it to be difficult to overcome this problem of theft of invention. But still various new laws have been implemented from time to time to overcome this issue. Moreover there has also been a challenge with respect to patenting of genes (Arnold and Eve, 2002).

Scenario of Patenting of Microorganisms

The microorganisms are widely used in production of various biotechnological products, right from the past till the present modern day world. Therefore the thirst to patent microorganism has been there from the past. In fact first patent for microorganisms was made by Louis Pasteur for the process of fermenting beer, on 28 January 1873 (Nair and Ramchandran, 2010). Patent filing for fermented products dates back to the early 1800s. The development of recombinant DNA technology (rDNA) also enforced patenting in biotechnology sector. In 1973, the first recombinant DNA was inoculated in a microorganism. Thereafter there was a competition in patenting of microorganism at the global level. But the patents for microorganism were overlooked as they were deemed to be the products of nature. In the landmark case of Diamond V. Chakrabarty a genetically modified

bacterium capable of breaking crude oil was granted patent (Diamond v. Chakrabarty, 1980). This decision encouraged the patenting of microorganisms that stimulated the growth of biotechnology industry.

Scenario of Patenting of Plants

In the year 1930 United States Patent act allowed patenting of plants basically those are ornamental and fruiting trees (Pardey *et al.*, 2013). Later on plant variety protection act (PVPA) was enforced in 1970. In 1985, United States Patent Appeals permitted protection for asexually, sexually and in vitro developed plants varieties. As the case of Hibberd in 1985, that involved a tryptophan overproducing mutant, the US Patent Office declared that plants could be patented (Chawla, 2002). By referring the case of Chakrabarty the US utility patents granted patents for genetically modified plants also. In an infringement lawsuit, J. E. M. Ag Supply, Inc. v. Pioneer Hi-Bred International, Inc., the United States Supreme Court in 2001 decided that plant utility patents could be granted to sexually reproduced plants under 35 USC §101 (Roberts, 2013). In case of transgenic plants, herbicide resistant and insect resistant cotton, potato, maize, soybean etc. have been patented. A case by Green Peace in the year 1995 was moved forward with reference to a patent on plants that contained a transgene, possessing herbicide resistance (Kumar, 2008). In 2003 the EPO granted patent to Monsanto for a wheat variety, Nap Hal which was indigenous to India (Sople, 2016). However, in 2004 the patent for this was revoked. In India the processes that involve producing disease free plants or incorporating certain characteristics in them are acceptable for patenting. In regards to Article 27.3(b) of the TRIPS agreement, plants and animals were not considered for the compulsions of strict patent regime. The members of TRIPS agreement were encouraged to protect plant varieties either by patents or by effective sui generis or both (Kochhar, 2004).

Scenario of Patenting of Animals / Transgenic Animals

In the year 1988, the University of Havard was issued the first animal patent for a genetically engineered mouse that contained cancer causing gene (Kevles, 2002). It was developed to study factors that stimulate susceptibility to cancer, to detect the carcinogenic agents that cause cancer and discover new cancer therapy. The patented animal was a eukaryotic animal that contained activated onco gene sequences to determine the probability of development of malignant tumors in animals. The onco gene sequence was introduced in the animal at the embryonic stage. A large number of patents for patenting of transgenic mice were filed, that were used for the study of diseases like ulcers, Alzheimer's disease, HIV infections, leukemia, sickle cell anemia etc. The most renowned patentable transgenic animals are those that are being produced by genetic engineering. These transgenic animals are developed by incorporating its DNA with the DNA from other animals or from human beings. Laboratories with big amenities are trying to produce new transgenic animals by inserting genes from one organism to other organism that includes microbes also. The microbes with recombinant DNA are being used as vectors for inserting genes from one animal to the other by using the techniques called as

microinjection, cell fusion, retroviral transformation etc (Moses, 1987).

Scenario of patenting of clones

In 1977, Dolly was the first cloned animal, cloned from somatic cell (Cibelli *et al.*, 2002). In case of patenting of animals some countries permits while the other reject. In Japan human cloning was rejected (2001). However it permitted scientist to use human embryos that were not developed by cloning. The Japan government science council granted permission for limited use of cloned human embryos only for scientific research. In this regard numerous countries like South Korea and Britain also permitted cloning of human embryos for therapeutic purposes (Isasi and Knoppers, 2006). In the United States human cloning is totally prohibited but that of animal cloning is permitted and also patented. The patents on the human embryonic stem cells have been granted in US while in Europe the stem cells patentability is still a controversial subject of debate. In Europe (1998), a directive (98/44/EC) was adopted on the legal protection of biotechnology inventions (Binns and Discroll, 1998). The EU Directive (98/44/EC) declares that its member states should harmonize their laws relating to the patenting of biotechnological inventions. The EPO has added the provisions of the EU Directive in their Implementing Regulations in 1999. The member states of the European Union were required to alter their national laws according to the directives of the European Union by 30 July 2000. It was only some countries that implemented the laws accordingly. In UK, the new 'Patent Regulations 2000' are in the Section 76 A of the UK Patent Act (MOPP, 2013).

Scenario of Patenting of Genetic Material (DNA / EST)

The recent advancement in the field of biotechnology has also been involved in the patenting of genetic material that includes DNA or genes or gene sequence. The United States patent law considers DNA sequences as chemical compounds, which are considered for patenting by USPTO (Milkov, 2013). According to the Utility Examination Guidelines, the USPTO stated that isolated and purified DNA molecule different from naturally occurring compound are eligible for patenting (Tin Wong and Kit Chan, 2014). It is also provided that the patented gene should have the utility criteria, in absence of which the patent shall be rejected. However, EPO (European Patent Office) differs in this respect of utility or usefulness criteria, which stipulates that for patentability inventor has to show its industrial application for grant of a patent. As per EPC, implementing regulations of EU (European Union) directive (98/44/EC) in 1999, the new provisions are summarized as follows (Kumar and Shekhawat, 2009): The definition of biotechnological invention, according to Rule 23b, is invention that concerns 'a product consisting of or containing biological material or a process by means of which biological material is produced, processed or used'. This includes DNA-related inventions, such as an isolated DNA fragment and the gene it encodes or DNA sequence analysis protocols and its software products. The definition of biological material is 'any material containing genetic information and capable of reproducing itself or being reproduced in a biological system'. For example, plasmid, which is simply a piece of DNA containing a group of genes which cannot reproduce by

itself, but it can be reproduced in a biological system, such as bacteria. The biological materials, such as, DNA, protein, plasmids, are patentable if the materials are isolated from its natural environment or produced by means of a technical process. Rule 23e further pronounces that the simple discovery of one of the elements of the human body, including the sequence or partial sequence of a protein or a gene, cannot constitute patentable invention if industrial application, i.e., utility, of the claimed gene or protein sequences or a partial sequence is not disclosed in the patent application. USA and Europe have permitted patents on all plants of a particular species into which a specific new gene is inserted by biotechnological means (Blackeney, 2012). In this way, a gene can be patented along with legal claims over the isolated gene and DNA sequences. In addition to this, USA and Europe have also granted patents on transgenic plants. According to Japan Patent Office, the patenting of only those inventions is allowed that helps in development of industries and that are useful and have industrial applicability (Tessensohn, 2014). The patent act, 1970 of India prohibits patenting of naturally occurring material, but patents that cover genetic material and gene sequences have been granted (Ravi, 2013).

Expressed Sequence TAG (ESTs)

An expressed sequence tag (EST) is a short sub-sequence of a cDNA sequence. ESTs can be used to identify gene transcripts, and are often applicable in gene discovery and in gene-sequence determination. The production of EST is one-shot sequencing of a cloned cDNA. EST can be used to identify an expressed gene. In 1990s numbers of ESTs were filed for patenting in US (The Ethics of Patenting of DNA, 2002). The first 'EST patent', 'Human Kinase Homologs' (US Pat No 5,817,479), was issued to Incyte Pharmaceuticals Inc. on 6 October, 1998 (Carmen and Hardiman, 2006). The patenting of genetic material and EST basically deals with the utility factor with respect to acceptability.

Scenario of Trips in Biotechnological Patenting

The trips agreement is an international agreement established by the WTO (World Trade Organization). In the year 1994, at the end of the Uruguay round, this trips agreement was discussed. The TRIPS was the first international law which legalized the patenting of life forms by the member states. The Article 27 (1) of TRIPS agreement grant patents for any invention in all fields of technology if it's new, involves inventive step and if it is capable of industrial application. The Article 27 (3) (b) of the TRIPS agreement deals with the biotechnological inventions (Yu, 2007). Article 27 (3) (b) of the TRIPS agreement cover one of the most controversial issues. It is often called as the "biotechnology clause" that depicts subject matter which Member states may exclude from patentability, but along with it, are also guidelines for Member states to grant patenting of microorganisms and certain biotechnological processes. Article 27.3(b) also describes that, Member states may also exclude from patentability: plants and animals other than microorganisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes (UNCTAD-ICTSD, 2005). However, it has been also stated that Member states shall

provide for the protection of plant varieties either by patents or by an effective sui generis system or by any combination thereof. Accordingly Section 3, of the Indian Patent Act 1970, that was amended which took microorganisms in patentable criteria (Goel and Parashar, 2013).

Evaluation of Requirement for Biotechnological Patenting

The biotechnology industries are of the favour that their inventions should be protected for commercial needs. The researchers and scientist working in the field of biotechnology also feel the necessity of patenting of their research or inventions. But in general in some countries the biotechnological inventions are fit for patents as they fit the ethics but others are controversial as they are referred as unethical and non patentable. The patenting of biological matter obtained or isolated directly is discarded from patent issue because of the reason of product of nature for example plants and animals cannot be subjects of patent. However, when these plants and animals are created by means of some biotechnological mechanism then they might be subjected to patent criteria. The patenting of modified microorganisms, genes or DNA can be considered. The biotechnological companies have been developing different biological products in the field of agriculture, medicine, pharmacy etc that are economically profitable. Therefore they are of the view to protect such products by patents laws. But excess of greed towards economic growth led to the plagiarism in the field of biotechnological inventions. Thus patenting requirement for biotechnological inventions is both favourable and unfavourable.

CONCLUSION

The present study depicts that commercialization of biotechnological inventions has intruded the patent war in the globe. The pharmaceutical giant companies due to competition have excelled plagiarism of biotechnological inventions. The enforcement of patent laws in the world has indulged plagiarism in the biotechnology sector. However, developed nations have been successful in patenting maximum biotechnological inventions in their favour. The awareness with respect to patent laws in the developing nations has been a boon in preventing plagiarism of their biotechnological inventions. Over all from this study it is concluded that patent laws plays a significant role in persuading and prohibiting plagiarism of biotechnological inventions.

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