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ANALYSIS OF PATENT LAWS WITH REFERENCE TO MICROORGANISMS

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ABSTRACT

The term microorganisms mean those organisms that are microscopic in nature or that cannot be seen through naked eyes, they consist of both single cell as well as cell clusters [1-2]. The microorganisms are microbiological entities, cellular or non-cellular, capable of replication and transferring genetic material. In the modern era microorganisms are being used to produce variety of biological products like vaccines, antibiotics, proteins, enzymes, beer, wines etc [3]. Various industries like the pharmaceutical, bakery, dairy and the breweries use specific strains of microorganisms for producing specific products [4]. Development of new strains of microorganisms to produce desired products has triggered competition among these industries to patent their respective strains of microorganisms. This has led to develop various patent laws throughout the world for patenting of microorganisms. The present study creeps in in-depth analysis of patenting of microorganisms.

KEY WORDS

Budapest treaty, Microorganisms, Patent laws, Trips agreement.

INTRODUCTION

The microorganisms are those living organisms that cannot be seen through our naked eyes. They can be viewed with the help of a microscope. The microorganisms include Bacteria, algae, fungi, protozoa, yeast, viruses etc. A patent can be described as an intellectual property right that is granted for a limited period to the patentee with the following conditions [5]:

- Full disclosure of his invention.
- Excluding others from making the patented product.
- Excluding others from using the patented product.
- Excluding others from selling the patented product.
- Excluding others from importing the patented product.
- Excluding others from process producing the patented product.

In other words, a patent can be described as the exclusive rights being granted to the inventor on certain conditions. The inventor is given sole right over the product for a limited period of time with certain terms and conditions. The basic purpose of patenting of microorganism is to encourage research to explore new microorganisms with commercial utility and human welfare. Various new methods have been developed to produce new life forms like genetically modified plants species, animal species, genes, cell line etc. These newly produced life forms when patented are called as bio-patents [6]. However, there is a big debate throughout the world for patents granted to microorganism. The Article 52 of the European Patent Convention (EPC) sets three conditions for an invention [7]:

- The invention must be new.
- The invention must involve an innovative method.
- The invention must be of industrial application.

Due to the reason that life forms are products of nature and not a human invention, the living organisms were not included in the patent laws. The doctrine of product of nature restricts patentability of material present in nature which includes microorganisms. The patent laws were basically framed for chemical and mechanical

inventions. The criteria of patenting of microorganisms induced genetic engineering of microorganisms. This shall generate new strains of microorganisms; those can be applied in industries for producing desired products that can be used for human welfare. The first patent for microorganisms was made by Louis Pasteur for the process of fermenting beer, on 28 January 1873 [8]. The most authentic decision with respect to patentability of microorganisms was made by the US Supreme Court in the year 1980 in Diamond v Chakrabarty case [9]. In this case the patent was granted for a genetically modified bacterium.

DIFFERENCE BETWEEN DISCOVERY AND INVENTION:

The patent law system provides protection in accordance with the invention and not in accordance with the discovery. There is a close similarity between discovery and invention. By just stating that some known material is found with some unknown properties, amounts to a discovery. However further adding to this statement along with the statement, that material further can be used for the purpose of making particular material and particular process, then this article shall lead to invention and it can be subjected to patent. Thus, it can be concluded from the above that when any microorganisms is discovered, it is not an invention but a microorganisms is referred as an invention only when it is genetically modified for producing a biological product, through a specific process. According to Section 2(1) (j) of the Manual of Patent Office Practice and Procedure, "Invention" means a new product or process involving an inventive step and capable of industrial application [10]. A discovery adds to the amount of human knowledge by disclosing something already existed which has not been seen before, whereas an invention adds to the human knowledge by creating a new product or processes involving a technical advancement as compared to the existing knowledge. If the discovery concludes that a material can be used for making a particular novel product through a particular process, then that material and the process could be patented [11]. In terms of patent laws 'Novel' means newly prepared that can be made available to the public [12].

PATENT LAWS PERTAINING TO MICROORGANIMS:

Trips agreement -

The trips agreement or trade related intellectual property rights agreement is an international agreement established by the WTO (World Trade Organization). In the year 1994, at the end of the Uruguay round of the general agreement on tariffs and trade, this trips agreement was discussed [13]. In the Trips agreement neither the microorganism is defined, nor it specifies any parameter concerning the scope of its protection [14]. There is no exact definition for microorganisms in TRIPS agreement to be patented. It becomes very difficult for the member nations of the TRIPS agreement when patenting microorganisms. The concept of 'microorganism' is extensively interpreted under the TRIPS Agreement. Patenting of it is permitted as applicable only to genetically modified microorganisms and not to those existing in nature [15]. The microorganisms shall be included in a broad sense of biological material that possess the property of self-replicable or replicable by the host. In that sense, the cellular material like plasmids, genes can be defined under the microorganisms. According to the TRIPS agreement, the patentable microbiological inventions include: (a) a process of producing a new microorganisms (b) a new microorganism produced by a defined process (c) a new microorganism *per se* (d) production of biological material which may include, vaccine, SCP (single cell Protein, antibiotic, enzyme, protein or any other such industrially useful product [16].

Budapest Treaty –

On 28 April 1977, in Budapest, Hungary an international treaty was signed for international recognition of deposit of microorganisms for the purpose of patenting. This came into force on 9 August 1980. However, it was amended on 26 September 1980 [17]. This Treaty is administered by the World Intellectual Property organization. The permission to access this treaty is open to the states party to the Paris convention for the Protection of Industrial Property held in the year 1883. Under the Article 9(1) (a) of the Budapest treaty, the Eurasia Patent Organization (EAPO), the African Regional Industrial Property Organization (ARIPO) and the European Patent Organization (EPO) have filed the declaration of acceptance. This treaty basically deals with the deposits of microorganisms at an international depository authority, which is recognized for the

purpose of patenting. The rule 13.2(a) of the Regulations under the Budapest Treaty, deals with the registered international depository authorities for the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure [18]. The deposition of the microorganisms should be only in the culture collection centers recognized by the IDA (International Depository Authority) that is in accordance with the Intellectual Property Rights. The Article 7 of the Budapest Treaty exhibits guidelines to become a International Depository Authority. It should be taken into consideration that any invention that involves microorganism, it is impossible to describe it completely. For this purpose, it was laid down in the Budapest treaty to deposit the biological material to a recognized institution. According to the Budapest Treaty a person who has applied for a patent does not need to deposit the biological material in all the countries where he wishes to obtain the patent but can deposit the biological material to any one recognized institution, that will recognize the biological material in all the countries that are party to the Budapest treaty. There is a wide variety of biological material that can be deposited under the Budapest treaty, which includes i.e. prokaryotic and eukaryotic cells, cell line, spores, genetic vectors like plasmids, viruses, and organism that can be used for gene expression.

THE LANDMARK DECISIONS ON PATENTING OF MICROORGANISMS:

The Sidney A. Diamond Commissioner of Patents and Trademarks Vs. Ananda M. Chakrabarty Case, 447 U.S. 303 (1980). -

This case was argued on 17 march, 1980 and decided on 16 June 1980. The Chief Justice Warren E. Burger wrote the decision. In the year 1972, Ananda Mohan Chakrabarty, a genetic engineer of General Electric Company filed a patent for bacterium that could consume petroleum spills [19]. The bacterium of the genus Pseudomonas in its naturally occurring state does not have the property to consume petroleum spills. But the genetic engineered bacterium of Pseudomonas genus was capable of breaking down the complex petroleum components. For this reason, Chakrabarty applied for a patent containing three claims; i.e. (i) he produced the bacterium (ii) an Inoculum composed of a carrier material and the bacterium (iii) the bacterial species itself. But according to the law the living things are subject matter of nature and therefore they cannot be patented. Thus, the decision on this was turned down by the patenting authority. Later on, Chakrabarty appealed against this decision to the board of Patent Appeals. But still there was no change in the decision and the patent was rejected. However, the United States Supreme Court overturned the former decision and granted the patent for the first two claims and rejected the claim on the bacteria on the grounds that they are naturally occurring. The Chief Justice Burger wrote, the interpretation of which says "Whoever invents or discover any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title [20]".

Dimminaco A.G. Vs. Controller of Patents and Designs Case (2002) -

Dimminaco A.G., a swiss company, developed a live vaccine against Bursitis. Bursitis is an infectious poultry disease that causes great loss to the poultry farm owners throughout the world. Dimminaco applied for this vaccine patent to the controller of patents and designs. But the controller of patents and design rejected the application by interpreting that the end product contained a living material and its procedure of development being only a natural process. Against this decision Dimminaco appealed to the Calcutta high court in 2002 [21]. The Calcutta high court gave landmark decision by accepting the patent for the process of manufacturing the vaccine though the end product contained a living organism.

SCENARIO OF PATENTING OF MICROORGANISMS AROUND THE WORLD:

Patenting in Europe: The European union defines biological material as "any material containing genetic information and capable of reproducing itself or being reproduced in a biological system" (Directive 98/44/EC of the European parliament and European council of July 6, 1998 on the legal protection of biotechnological inventions) [22]. The controlling legislation for biotechnological inventions has been incorporated in the European Biotechnology Directive, adopted in 1998. The legislative provisions of which, are briefly described as [23]: Article 1 states that member should protect biotechnological inventions under national patent law and, if necessary, they should adjust their national patent laws to take account of the provisions of the directive obligations arising under the TRIPs (Trade-

Related Aspects of Intellectual Property Rights) agreement. In Article 2, "biological material" means any material containing genetic information and capable of reproducing itself or being reproduced in a biological system. It therefore includes nucleotide sequences i.e. full-length genes, complementary DNA (c DNA), and fragments thereof. The Article 3 deals with the patentability of biological material, which confirms that novel, inventive, and industrially applicable (broadly corresponding to "useful" in 35 USC §101) inventions are protectable by patents. The Article 5 deals with the biological material from the human body. However, the sequence or partial sequence of a gene isolated from the human body or otherwise produced by means of a technical process may constitute a patentable invention even if its structure is identical to that of a natural element. The Europe has appreciably differentiated the microorganisms from the biological material for the purpose of patenting of microorganisms.

Patenting in United States of America:

The US patent system involves the concept of creativity and utility and uses its strict interpretation [24]. In United States, a discovery unless accompanied by an element of creativity is not an invention. For example, a bacterium producing digestive enzymes is not patentable. However, a genetically engineered bacterium that is capable of breaking down crude oil into its basic components is patentable (Diamond v Chakrabarty). The United States has straight forward guidelines for granting a patent i.e. if you have a new, novel, non-obvious idea that has a utility, patent is granted.

Patenting in China:

The patent of microorganisms is allowed in china. In china, DNA sequences may be patented as large chemical compounds/composition of matter. China has a product of nature rule that renders naturally occurring DNA sequences unpatentable. Legal interpretation however has resulted n patentability claims that cover purified and isolated DNA sequences as new composition of matter. Certain Rules relating to inventions in the biological field in China include [25]:

I. Embryonic stem cells, germ cells, oosperms, and embryos of human beings shall not be granted patent rights.
II. A gene or a DNA fragment *per se* and the process to obtain it can be patented if the gene or DNA fragment is unknown in the prior art and can be accurately characterized and exploited industrially.
III. A vector, a recombinant vector, a transformant, a polypeptide or a protein, a fusion cell, a monoclonal antibody, the preparation method and its use are all patentable.

Thus, in China procedure involves purify, isolate and the patent granted.

Patenting in Japan:

The Japanese patent office has divided biotech inventions into four distinct areas [26]: genetic engineering, microorganisms, plants and animals. From a patent perspective microorganism means yeast, bacterial, actinomycetes, moulds mushrooms, unicellular algae, viruses, protozoa and also undifferentiated animal or plant cells as well as animal or plant tissues cultures. Therefore, in Japan patenting involves defining and then patenting.

Patenting in Australia:

To encourage patentable subject matter under Australian law, an invention must give rise to an artificially created state of affairs that is in a field of economic endeavour [27]. IP Australia explains on its website that the following types of subject matter can be considered in a standard patent: isolated bacteria, cell lines, hybridomas, related biological materials and their use, and genetically manipulated organisms [28]. In Australia the standard patents can be obtained for biological material. According to the Patent Manual of Practice & Procedure, directions to examine patent applications, states [29]: that, a micro-organism, protein, enantiomer or antibiotic discovered in nature can be claimed in its isolated form, or as substantially free of (specified) impurities. In Australia patentability of microorganisms has been considered and the following principles can be derived [30]:

- a new organism just cannot be rejected on the ground that it is something living.
- Any new claimed organisms must be improved or altered exhibiting useful properties.
- Naturally occurring micro-organisms per se are not patentable as they represent a discovery and not an invention.
- A claim for a newly derived pure culture of the micro-organism would be granted for technical invention.

Therefore, in Australia for a patent you have to isolate and then develop it.

Patenting in India:

The foundation of the Indian patent system was laid down years back under the British colony in 1856 [31]. Later, India inherited the Patent and Design Act 1911 from the British colony which provided protection to all inventions except invention related to atomic energy. The act was revised post-independence so as to facilitate the needs of industrial community and to promote the stage of development of the country. In the year 1958, Justice Rajagopal Ayyangar Committee recommended various recommendations on which the patent act 1970 was based [32]. The supreme court of India in Bishwanath Prasad Radhey shyam v Hindustan metal industries held that the fundamental object of patent is to promote scientific research, new technology and industrial progress [33].

India became member of TRIPS agreement in 1995, to meet minimum IPR standards. India made three amendments in years 1999, 2002, 2005 to fully comply with the requirement under the trips. The main objective of the Patents (Amendment) Act 1999 is to remove exclusion of product patents in the area of food, medicine and drugs. The Patent (Amendment) Act, 2002 added explanation to chemical process. It stated, "Chemical process includes biochemical, biotechnological and microbiological process". In the Case of Dimminaco AG v Controller of Patent Design, Calcutta high court of India has raised the issue that whether a process that involves microorganisms as an end product can be patented or not. The court concluded to accept the process of manufacturing bursitis vaccine as patentable subject matter under section 5 read with section 2(1) (j) of the act even though the end product contained a living organism [34]. This historic decision opens the way for numerous such inventions related to microorganisms. In Indian context this decision has helped in expansion of biotech industries.

However, after the patent amendment act 2005 India recognizes two categories of patent, product patent and process patent. Moreover, in the patent amendment act 2005 patent application through "mailbox" was introduced [35].

CONCLUSION

The granting of patents to living organisms is to protect the rights of inventions. This encourages advanced research and development and prohibits biopiracy. In other words, the product of biopiracy should not be granted patents. It would thus be in our national interest to document, protect and modify new microorganisms isolated from various parts of our country and find their new and improved industrial uses. The most important issue with respect to microorganisms patenting, is about the definition of microorganism. As we know that neither in the domestic laws of our country nor in any international instrument the definitions of microorganisms is clearly provided. In such a case reference may be given to the Vienna convention of law of treaties, 1969 [36]. It states that in the absence of any definition of any term in the treaty the basic rule of interpretation may be applied. In this respect, the dictionary meaning of microorganisms would be sufficient to distinguish plants and animals from microorganism, by the WTO members to TRIPs agreements. Thus, it can be concluded from the present analysis that patenting of microorganisms is granted with the conditions that they have been altered to generate some useful biological products through a specific process, for human welfare.

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