

ECOLOGY OF INDIVIDUAL ORGANISMS, BIOTECHNOLOGY PATENTS AND ITS ENVIRONMENTAL IMPACTS

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DISCLAIMER

This is a part of my PhD curriculum in my university and am a research scholar in VIT University. It is a requirement for our award of PhD degree. And I also wish to add my guide as co-author of this research on whose guidance I have done this paper and its her ideas which I have enlightened in my research paper.

Abstract:

Earth has a wide range of living organisms inhabiting them which includes plants animals living organisms and human-beings. They might belong to different classes and species based on their livelihood and habitat and special characteristics. All living forms co-exist in the same habitat with each other even with different characteristics and lifestyle. Living organisms include micro-organisms and their habitat. This paper is about the classification of micro-organisms and ecology of micro-organisms and patents on micro-organisms and its environmental impacts. We will see in detail about the need for classification of various types of micro-organisms, their ecology in aquatic and terrestrial environments, the procedure to patent micro-organisms. The various types of micro-organisms include bacteria, fungi, virus, protozoa. The emerging concept of biotechnology patents and its legal perspective and its necessity in the future. The essentials for a patent will also be dealt in detail and the patentability of micro-organisms and we will discuss about the various case-laws in detail with issues regarding biotechnology patents in the purview of genetic engineering and also about the environmental impacts. The environmental impacts are also both positive and negative and are related to economic growth and technology.

Keywords: Habitat, micro-organisms, ecology, environment, patent, genetic engineering, biotechnology.

Introduction:

The study of micro-organisms or microbes is called micro-biology. This study deals with the study of living organisms so called micro-organisms, which include bacteria, fungi, algae, protozoa and virus. Microbes are living in aquatic and terrestrial habitat and some have capability to survive long in extreme habitats like hot springs, ice sheets and high salt water bodies, etc. Some of the micro-organisms are beneficial to us and good for our health and they are used in preparation of curd, bread, cheese, vaccines, vitamins while others are harmful causing diseases to animals, plants and human beings. Micro-organisms differ from each other in many features like size, colour, habitat, metabolism, etc. They may be classified as unicellular (amoeba, paramecium, bacteria) and multicellular (fungi). Types of microbes include bacteria, virus, fungi, algae, protozoa.

Objectives of the study:

1. To study in detail about the types of micro-organisms and its classification.
2. To analyse the essentials of patent and patentability criteria for micro-organisms.
3. A detailed case- study on various biotechnology patents and its environmental impacts.
4. To give suggestions based on the analyzation of laws and case-study done.
- 5.

Methods and Materials:

The researcher has used the Doctrinal Research methodology. Under the Doctrinal Research Books, Journals, Articles, Magazines, All India Report, Supreme Court cases were used. These materials were collected from various libraries like Connemara library at Egmore, Anna library at Kotturpuram, British Council library Chennai and The TamilNadu Dr. Ambedkar Law University, Chennai. The various other sources for this research include online journals and publications.

Protozoa

A protozoan is a unicellular eukaryote. Eukaryotes are organisms with a cell which is surrounded by a nucleus enclosed within a nuclear envelope. The word unicellular means a single cell. They are included under the kingdom of **Protista**. They are found in

ponds, rivers, oceans, lakes, and in moist soil. They range from 2-200 microns in size. Protozoans have specialized organs called organelles. These organelles are used for movement, feeding and other purposes.

The protozoans are classified below based on their locomotive characteristics into four types:

Pseudopod- presence of pseudopodium for locomotion. (eg. Amoeba)

Ciliates- presence of cilia for locomotion. (eg. Paramecium)

Flagellates- presence of flagella for locomotion. (eg. Euglena)

Sporozoans- parasites (eg. Plasmodium).

Let us see about these four classifications in detail

Amoeba

Amoeba is a unicellular organism which is microscopic in nature. It is found in ponds, lakes, rivers, wetlands. It is irregular in shape. It has a cytoplasm, nucleus and a cell membrane. The cytoplasm is the thick solution that is filled in each cell and is covered by a cell membrane. The nucleus is the centre of the cell and it regulates the activities of the cell. It moves with the help of pseudopodia which means 'false feet' in Latin. Pseudopodia are the extended part of cell membrane which help them to have their food. The body moves around the food particle and swallows it and forms the food vacuole. Contractile vacuoles which are found in the cytoplasm help in excretion. Amoeba reproduces through fission and sporulation methods.

Paramecium

Paramecium are also unicellular organisms. They are mostly found in freshwater and marine environments and are found in abundance in stagnant lakes and ponds. Paramecium vary in length from about 0.05 to 0.32mm (0.002 to 0.013 inches). They are in a slipper-shape pattern with cilia fully covering the body. Cilia means short hairy extensions which is used to help in locomotion. They can spin, swim forward and backward in water. They are short and have a round posterior end. They are used to cure cryptococcus disease. Paramecium primarily feed on bacteria and yeast.

Euglena

Euglena is found in fresh water and salt water. It moves with the help of flagella. Flagella or flagellum means large number of delicate hair-like projections of different lengths that come out from the cell wall. These are created mainly to help in locomotion. It can be found in many shapes like U-shaped, ribbon-shaped, elongated, cylindrical, etc. These are also called parasites because they can cause serious blood and tissue related diseases like "African Trypanosomiasis" which is also known as sleeping sickness and "leishmaniasis" means disfiguring colour infection.

Plasmodium

Plasmodium belongs to a class of sporozoan which means parasitic in nature. It helps in spreading diseases like malaria by injecting the vertebrate host with a bite. It consumes haemoglobin and red blood cells for its survival.

Bacteria

Bacteria are unicellular micro-organisms. they are prokaryotic in nature. The study of bacteria is called Bacteriology. Bacteria was first discovered by Anton Von Leeuwenhoek a Dutch scientist in 1676.

They exist in four major shapes: bacillus(rod shape), coccus(spherical shape), spirillia(spiral shape), vibrio(curved shape). They are prokaryotic organisms which do not have a nuclear membrane and membrane bound organelles. The genetic material is called nucleoid. The cell wall is made up of polysaccharides or polycarbohydrates and protein. Most of them do not have chlorophyll so they are heterotrophic in nature but some are autotrophic and possess bacteriochlorophyll(chromatium). They reproduce in the form of binary fission and formation of endospore. They can have few variations which are due to genetic recombination which is achieved through conjugation, transformation and transduction. The bacterial cell has three layers, they include the cytoplasm, cell wall, and the capsule(glycocalyx). This capsule means gelatinous substance composed of a type of polysaccharides or polycarbohydrates or polypeptide or both. A thick layer of glycocalyx is bound tightly to the cell wall. This sticky nature allows them to get attached to substrates of plants and root surfaces.

Virus

The term 'virus' comes from a Latin word which means 'venom' or poisonous fluid. This is mainly used in spreading diseases among plants, animals and human-beings. A virus is a very tiny particle which is made up of genetic material and protein. They have a nucleus and it is surrounded by a protein coat. Viruses contain only DNA or RNA in a native state. The study of viruses is called virology.

Many diseases are spread through viruses like Hepatitis B, Chicken pox, smallpox, measles, mumps, common cold, etc. Generally, viruses are ultramicroscopic particles which means they are smaller than bacteria and its size is in range from 20 to 300nm in diameter. (1nm = 10^{-9} metres) approximately. It is said that bacteriophage measures about 10-100nm in size. It is classified into three types based on shape and symmetry.

1. Cuboid symmetry- eg. Adeno virus, Herpes virus
2. Helical symmetry- eg. Influenza, tobacco mosaic virus (TMV).
3. Complex or Atypical-eg. Bacteriophage.

Fungi

The word fungi are derived from a Latin meaning 'mushroom'. They are existing in both unicellular and multicellular forms. The study of fungi in detail is called mycology. The fungi are made up of thin filament-like branch structures called hyphae that help to absorb material. A number of hyphae combine together to form mycelium. The cell wall is made up of chitin and fungal cellulose. They collect nutrients by sucking up the organic material from their common environment (decomposers) through relationships with plants or with a host. Fungi reproduces by the process of releasing spores.

Algae

Algae are also called cyanobacteria or blue-green algae. They survive in aquatic, marine and freshwater. There are many varieties of algae found in sponges, shells, soils. Algae which grow in snow are called cryophytic algae and are red in colour. Algae grown on plants surface are called epiphytic algae. The detailed study of algae is known as phycology. They are unicellular or multicellular eukaryotes that obtain energy with the help of photosynthesis. There are three main types of algae like red algae, brown algae, green algae. They live in water, damp soil, rocks. They also help to production of oxygen and carbohydrates which are in turn used by other organisms.

Essentials of a Patent

The Indian patent law has some essential criteria for an invention to get registered under this act and enjoy the protection for a period of twenty years. When this protection period is over the invention comes into the public domain. The three main essentials are novelty, inventive step, Industrial application.

Let us see about these three essential criteria in detail.

Novelty

The term novel means "new". It means that the invention should be a new product or process. The term new invention is defined in sec 2(1)(j) in which a "New invention means any invention or technology which has not been anticipated by publication in any document or used in the country or elsewhere in the world before the date of filing of patent protection with complete specification, *i.e.*, the subject matter has not fallen in the public domain or that does not form part of the state of the art."¹

Inventive step

Inventive step is defined under sec 2(ja) of Indian Patents Act 1970, as "a feature of an invention that involves a technical advancement as compared to the existing knowledge or having economic significance or both and that makes the invention not obvious to the person skilled in the art"².

Industrial application

Any invention that is to be registered must be beneficial to the public at large and it can also be useful to industries. It is a very common essential feature that needs to be fulfilled by the inventor to get patent protection.

Biotechnology Patents

Biotechnology is the study of science in developing techniques for the applying the biological processes and organisms to produce the materials used in any industry. The term implies the use of genetic engineering to do modification of the bacterial cells to formulate a fully developed new substance or to introduce a novel innovative creature in animals and plants. As biotechnology inventions have been composed through reunification of DNA technology, they involve a huge investment in research and development and hence there is a need to protect the inventions by way of granting patents and protecting the interests of the investor.

Biotechnology is defined in Webster's dictionary as "the manipulation (as through genetic engineering) of living organisms or their components to produce useful and commercial products (as pest resistant crops, new bacterial strains, or novel pharmaceuticals); also, any of the various applications of biological services used in such manipulation"³.

Genetic engineering

Genetic engineering is the direct experimentation of an organism's genome using biotechnology. It is done mainly to change the genetic arrangement of cells and its natural characteristics. It also includes transfer of genes to create improved or novel organisms. It is also known as genetic modification.

It is the process of adding a new DNA to an organism. The main goal is to add one or more new traits that are not already found in that organism and make it different from others with its own unique features and it can claim as a novel invention with inventive step and its own industrial application which are the essentials to get patent protection.

Patentable subject matter.

The Indian patent law provides certain provisions under section 3 and 4 as non-patentable subject matter which includes micro-organisms as a patentable subject matter.

¹ Definition under sec 2(1)(j) of Indian Patents Act 1970.

² Definition under sec 2(ja) of Indian Patents Act 1970.

³ Merriam Webster's dictionary, 11th edition 2020.

“plants and animals in whole or any part thereof “other than micro-organism” but including seeds, varieties and species and essentially biological processes for production or propagation of plants and animals.”⁴ This provision clearly tells us that Indian law includes micro-organism as patentable subject matter accordingly if the basic requirements necessary to get patent protection are fulfilled by the inventor.

Case study on biotechnology patents

The following are case-laws related to biotechnology patents in USA and India.

Diamond v. Anand Chakrabarty

The concrete idea of the patent application states:

“This human-made, genetically engineered bacterium is capable of breaking down multiple components of crude oil. Because of this property, which is possessed by no naturally occurring bacteria, Chakrabarty’s invention is believed to have significant value for the treatment of oil spills”⁵.

“There were three types of patent claims; first the process claims for the method of producing bacteria; second, claims for an inoculum that comprised a carrier material floating on water, such as straw, and the new bacteria; and third, claims to the bacteria themselves”⁶.

“The patent examiner at United States Patent Trademark Office (USPTO) allowed the first two groups but rejected the claims directed to the bacterium as unpatentable under 35 US Constitution (USC) Section 101. The USPTO rejected the claim on the bacterium on two grounds; first, bacteria were ‘products of nature’ and second, bacteria as ‘living things’ cannot be patentable. Chakrabarty made an appeal against the rejection of these claims to the Patent Office Board of Appeals. The Board of Appeals reversed the first ground of rejection, mentioning that that the claimed bacteria were not products of nature, as they had been modified to produce a combination of plasmids that no known bacterium produced”⁷.

Dimminiaco A.G v. Controller

It is an Indian caselaw filed in the Calcutta High Court. The invention is regarding a process for preparation of vaccine for an infectious bursal disease found in poultry. The vaccine was beneficial for protecting the poultry from this infection. At the initial stage the patent application was rejected on the ground that the claim did not constitute an invention. In this case the Calcutta High Court found that the word manufacture was not defined in the Patents Act. “Hence the court explained the term usage or industrial application in this case. The Court held that the Manual of Patent office Practice and Procedure, states that,

‘living entity of artificial origin such as micro-organism, or vaccines are considered patentable, although higher life forms such as plants or multi-cellular animals, whether of natural or artificial origin, are not. Moreover, biological material such as recombinant DNA, Plasmids and processes of manufacturing thereof are patentable provided they are produced by substantive human intervention”⁸. In addition, the processes relating to micro-organisms or producing chemical substances using such micro-organisms are patentable.

Environmental impacts

The environment refers to the surrounding or the eco-system which we live in. There are various impacts on the environment. Any change in the human environment may affect the nature leading to changes in the climate and various other factors. The basic impact on an industry is to the extent to which it permits patents on genetically engineered organisms which will help to stimulate both their development and the growth of the industries which are employing them. To ascertain this exactly first it requires an examination of the theory and clarification regarding the social policies in the patent system.

Although biotechnology was known long back, when fermentation was used to produce beer and make bread with the yeast formation, the economic interest in biotechnology has increased to a huge extent. The arise of modern biotechnology as a result of the development of monoclonal antibody technology and techniques of molecular biology and recombinant DNA to create antibodies to prevent and protect us from infection of deadly diseases. It is also used in biotechnology based pharmaceuticals as recombinant erythropoietin used for stimulating the growth of red blood cells and growth hormones, the process genetic engineering to plants for finding unique and new varieties and animals as transgenic varieties with resistant development.

Medicinal plants are a great valuable source for agriculture and industrial aspect. However, their cultivation and collection in many places are still an issue in progress based on the local governing bodies and their regulatory laws. Protection of certain traits such as higher yield, or higher content yet is also a recent problem. Recombinant DNA technology makes it possible to selectively do modification on the genetic material of higher organisms. Genes can be transferred between various species of organisms and different organisms that are not even closely related. It can be two different creatures like bacteria and mice. Existing genes can be cut and changed to form new gene combinations with new and improved functions. This process of genetic engineering has its

⁴ Sec 3(j) of Indian Patents act 1970.

⁵ A. Chakrabarty, ‘Microorganisms having multiple compatible degradative energy-generating plasmids and preparation thereof’, (1972) U S Patent No: 4,259,444.

⁶ 447 US 306 (Diamond v. Chakrabarty).

⁷ Diamond v Chakrabarty, Research at IDRL. <http://www.springer.com/research.html>.

⁸ Research at IDRL. <https://www.scribd.com/document/255078250/Biotechnology-Patenting-in-India-and-Related-Issues>.

own need based on its positive impacts like vaccinations for diseases. But it can be negative at the same time if it is used in spreading harmful diseases to nature and mankind. Based on its impacts it can be increased in production or banned by the government from production.

RESULTS AND SUGGESTIONS

The patent law needs to be specific with regard to the inventions which are allowed to get patent and those which are not allowed to get protection. The treaties and conventions need to be more specific in regard to the protection of micro-organisms. The patent law needs to be modulated and sui generis system needs to be followed to protect micro-organisms if necessary. These micro-organisms must be beneficial to the public.

There should be a separate procedure to register the patents on micro-organisms because they need some special attention. The micro-organisms may be harmful in most of the circumstances and may be hazardous to the environment. They have the special quality of propagating very fast and so they can spread diseases faster. So, any instant remedy must be followed to prevent this and safeguard the public.

The term patent protection being 20 years must be stringent and the evergreening of patents must not be allowed in other countries also. Evergreening of patent means making certain modulations in the old invention and increasing its efficiency and claiming patents. It is allowed in U.S.A. The micro-organism which are being used for harmful purposes must be destroyed and it should be done in a legal manner. The inventions if it affects the environment, it should not be patented.

Conclusion

The micro-organisms are also living organisms and so they cannot be used for any illegal purposes or spreading harmful diseases and killing human-beings. In this covid era, the ambience of biotechnological development, mostly requires rigorous hard work and research and collection of material and methods in order to have a better understanding about the implications of biotechnological patents and the difficulties faced in patenting them. Harmonization of such conflicting opinions of various other countries must be the guiding aspect and the key for permitting such inventions or innovations, in this field of biotechnology for grant of patents regarding micro-organisms.

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