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A Study on Patenting of Micro-Organisms

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ABSTRACT

Numerous facets of trademark protection in the context of biotechnology inventions are becoming hotly debated topics both domestically and globally. The issue that is of pressing importance at hand is: Whether Micro-organisms can be granted protection under Patent? The legal frame work in many countries with regards to patenting of micro-organisms is that the micro-organisms are not specifically excluded from patentability, however, in many circumstances micro-organisms are excluded from grant of patent protection on the ground that it is *"in opposition to established natural rules. Therefore, the main goal of this work is to comprehend and investigate the legality of microorganisms and the significance of doing so.* This work also makes a comparison for a better understanding of the topic.

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1. INTRODUCTION

In recent years, the fields of molecular science, inheritance, biophysics, cell biology, and immunology have made astounding strides and created a plethora of opportunities for the creation of innovative technology. Numerous facets of safeguarding proprietary information in the context of biotechnology inventions are becoming hotly debated topics both domestically and globally. The issue that is of pressing importance at hand is: Whether Micro-organisms can be granted protection under Patent? The legal frame work in many countries with regards to patenting of micro-organisms is that the micro-organisms are not specifically excluded from patentability, however, in many circumstances micro-organisms are excluded on the grounds that it is "contrary to well-established natural laws," from being granted patent protection. Microorganisms can be patented under the European Patent Convention (EPC) and the United Kingdom Patents Act, 1997. Microorganism patents are granted by the European Patent Office (EPO) and the British Patent Office. This is also evident in the United States' patent rules, when a microorganism was granted patent protection in 1980. The U.S. Supreme Court's 1980 decision to grant patent protection to genetically modified microorganisms and the subsequent creation of the WTO-IPR regime, which includes provisions for patenting invented living organisms, have brought up a number of socio-legal and ethical concerns about the direction of bioscience research [1].

2. WHAT IS BIOTECHNOLOGY?

Biotechnology, as defined by the Merriam-Webster dictionary, is:

"Modifying living things or their constituent parts (for example, through genetic engineering) to create typically commercial, beneficial goods (i.e., novel bacterial strains, pest-resistant crops, or innovative medications); any of the several biological science applications utilized in this process. In its fundamental form, biotechnology is biology-based technology; which employs cellular and molecular processes to create goods and technologies that improve both human well-being and the condition of the world. Traditional

biotechnology was mostly limited to three main fields; there has been a paradigm change in industrial microbiology, plant breeding, and animal breeding. Plant, animal, and human life have completely changed as a result of recombinant DNA, protoplast fusion, and hybrid technologies. More than 250 biotechnology-based therapies and vaccines are currently available to sufferers worldwide; the majority of these are for illnesses that were previously incurable. Agricultural biotechnology is used by over 13.3 million farmers globally to increase yields, safeguard products from pests and insects, and lessen the environmental impact of farming. Due to the development of biotech, the contemporary age has witnessed a breakthrough in both science and technology. It provides new products and technologies to combat diseases, improvement in crop yields, and improvement in the processes used in the industries, increased food safety with anti-microbial packaging, as well as using of microbes so as to clean oil-spills.

HOW BIOTECHNOLOGY IS HELPING THE SOCIETY

Recent developments in biotechnology are assisting society in overcoming its difficult obstacles. This is how biotechnology is helping the society:

Utilizing nature's own toolkit, biotechnology guides research directions and exploits our genetic makeup in order to heal the globe;

- Changing the outlook for serious, life-threatening illnesses that affect millions of people worldwide, lowering the prevalence of infectious diseases, and saving the futures of millions of children.
- Biotech uses biocatalysts, such as enzymes, yeasts, as well as other microbes, and biological processes such as microbial fermentation, to build miniature manufacturing operations. Biotechnology assists the world's energy supply via: • Simplifying chemical manufacturing procedures by at least 80%.
- Customizing therapies for all the patients to adverse effects and reduce risks.
- Reducing the emission of greenhouse gases by at least 52% through the use of biofuels.
- Boosting efficiency of manufacturing process to save 50% or more in operating costs.
- Herbicide tolerance, crop resistance, and the adoption of eco-friendly farming methods are all enhanced by biotechnology. By producing large crop yields with fewer inputs, biotechnology assists the world's food supply.
- Leveraging conventional biomass waste products to their maximum potential.
- Creating crops with better nutritional profiles to deal with dietary shortages in vitamins and other nutrients
- Manufacturing food devoid of waste product such as mycotoxin and allergies.
- Improving the amount of oil in foods and crops to support a healthier heart [2].

After understanding the meaning of biotechnology and what biotechnology is all about, including the usefulness of biotechnology to the society at large, we can come to the conclusion that biotechnology is a blessing to the field of science and technology. It provides solutions to problems that science alone or as a matter of fact technology alone cannot solve. However, while biotechnology is a blessing indeed it also raises serious issues with regards to public morality. The historic case of mammal cloning serves as an example of this. The entire world has been caught off guard by claims about human cloning. Human cloning remains a murky topic with many ethical and legal concerns.

WHAT ARE MICRO-ORGANISMS?

Micro-organisms were discovered in the 1670s by **Antoine Van Leeuwenhoek**. Later in the 19th century, **Louis Pasteur** found that micro-organisms caused food spoilage. In 1876, **Robert Koch** found that micro-organisms caused diseases [3]. Microorganisms, often referred to as microbes, are living things that are too small to be visible without a microscope. According to the traditional definition, microorganisms are living creatures that are too small to be seen with the human eye; They may consist of one individual cell or a group of interconnected, distinguishing cells [4].

Types of micro-organisms:

- Bacteria are unicellular, which prokaryotic microorganisms that do not have chlorophyll pigments.
- Viruses are extremely small, non-living, living particles made entirely of nucleic acid (DNA/RNA) with a protein coat called as a capsid surrounding it.
- Protozoa: These are unicellular, gukaryotic microorganisms without a cell wall.
- Microscopic fungi: These are heterotrophic, eukaryotic microorganisms that lack a circulatory system and do not exhibit any cellular development into actual tissues like roots, stems, or leaves.
- Microscopic algae: These are eukaryotic, autotrophic microorganisms without a circulatory system that do not exhibit any cellular development into real tissues like roots, stems, or leaves. Comparable to tiny fungus.

3. POSITION OF MICRO-ORGANISMS

In our day to day lives, micro-organisms are present everywhere. Even though they are extremely tiny and invisible to the human eye, their presence is extremely valuable. Because various microorganisms engage in different activities, they have varying effects on life. In addition to fixing nitrogen in the soil, microbes also aid in fermentation and the recycling of dead materials by breaking them down into simpler forms. However, it's also critical to remember that some microorganisms are dangerous to humans and can infect plants and animals. Degrade certain materials, like as rubber, can spoil food or food ingredients stored under normal circumstances. It is crucial to remember that different tumor-forming cell lines and antigenic organisms are not typically included in microorganisms. Microorganisms are naturally occurring living things. However, monoclonals and tumors are created under stress or with human assistance.

Patent Protection of Micro-Organisms in the United States

In the area of patents, the US is regarded as a "trend setter." In the United States, it is commonly believed that everything on the planet is patentable. The world was shocked in 1980 when the United States gave patent protection to a "bacteria that eats oil." The United States' patent law promotes and rewards creativity and invention. In the case of Diamond v Chakraborty [5], Dr.AnandChakraborty attempted a patent for crude oil-degrading living things that have been genetically modified. Three different types of claims were included in a filed patent application. The first two claims were in the form of methods: how the bacterium was made and how it was used to eat oil. The third claim category focused on the actual bacteria, stating that it was a genus of an already-existing bacterium but was distinct due to its genetic modification and the presence of two plasmids. The US patent bureau rejected this final claim, stating that the organism at issue was an organic substance or, instead, that it was a living entity and not covered by Title 35 US Code 101. Only recently created compositions of matter are eligible for patent protection under Title 35. Eventually, the Supreme Court took up the issue and reversed the examiner's decision, stating that genetic research will continue regardless of whether a microorganism is granted or denied patent protection. This landmark ruling by the US Supreme Court ushered in a new era of US patent law.

The court contrasted under ***Funk Bros.Seed Co v Kalo Inoculan[6]*** stating:

"In contrast, the patentee has created novel bacteria that differs significantly from those found in nature and has the potential to be extremely useful. Since his discovery is his own and not the result of nature's craftsmanship, it is patentable under section 101 of the US Code. However, according to the dictionary, the Court has interpreted the word "manufacture" in section 101 to mean "the production of articles for use from raw materials prepared by giving these materials new forms, qualities, properties, or combinations whether by hand labor or machinery."….." thereby shows that the bacterium was simply 'manufactured' and not 'invented'. In choosing such words the court suggests that Section 101 of the US code has limits and that it doesn't embrace every discovery. The abstract ideas, laws of nature, and physical phenomena have held not to be patentable. The considerable difference was not between inanimate and living things but between natural creation, whether living or not, and human-made products.

The court laid down some tests on account of the abovementioned case. The tests put forward by the court are as follows:

- "The laws of nature, physical phenomena and abstract ideas" are not patentable subject matter.
- A "non-naturally occurring manufacture or composition of matter-a product of human ingenuity-having a distinct name, character, and use" is patentable subject matter.
- "A new mineral discovered in the earth or a new plant found in the wild is not patentable subject matter."
- "The production of articles for use from raw materials prepared by giving to these materials new forms, qualities, properties, or combination whether by hand labour or machinery" is a 'manufacture' under section 101.

In ***Allen, Ex p[7]***. The Board concluded that a pacific coast oyster would be the official subject of patent under section 101 of the U.S Code if all the criteria of patentability was satisfied.

Patent Protection of Micro-Organisms in the United Kingdom

Microorganisms can be patented under the U.K. Patents Act of 1977. Microorganisms are granted patents by the British Patent Office. Although living things are not specifically excluded by the UK Patents Act, microorganisms were not considered a method of fabrication. Only a manufacturing method was eligible for security underneath the Act.

The primary focus of the "manufacture" argument surrounding the British case was perceived in the agriculture sector. The ***Standard Oil Company*** allegedly tried to protect "a method" of creating an enhanced

tract of agricultural land by applying a well-known microorganism with a hydrocarbon compound as a discriminating weed killer in a 1951 case [8]. Because there was no vendable product that was extremely similar to the specified technique, this application was denied.

4. THE BUDAPEST TREATY

The living substance of biological inventions cannot be sufficiently described, and the invention cannot be replicated without the biological material. It is now generally accepted that all biological substances ought to be stored in internationally recognized storage facilities as a result. For the sake of the patent process, the Budapest Treaty on the International Recognition of Deposit of Micro-Organisms was created. Because culture collections are designated as International Depository Authorities (IADS) under the treaty, a new bacterium stain can be stored for the purpose of filing obtaining a patent in every participating the government.

Trips Agreement

Member states may refuse patents for "plants and animals, other than micro-organisms and essentially biological processes for the production of plants and animals other than non-biological and microbiological processes" under Article 27(3)(b) of the TRIPS Agreement. Consequently, all signatory parties to TRIPS are required to extend patents to microbiological processes, non-biological processes, and microorganisms. Additionally, Trips may obtain patents for biological entities because the exemption does not apply to modified plant and animal parts or animal parts [9].

5. PATENT PROTECTION OF MICRO-ORGANISMS IN INDIA

In India patent protection is granted under the Patent Act, 1970. With regards as to what inventions are patentable it is governed under Chapter II of the act under section 3. Section 3(j)'s exclusion clause allows pathogens to be granted patents. This section talks about what inventions are not patentable but when it comes to describing micro-organisms it uses the words “other than micro-organism”. This is why microorganisms can be patented under the Patent Act of 1970, as revised in 1999 and 2002. In India, the Patent Act of that country was essentially silent on the trademarking of living matters until the amendments in 1999 and 2002. But we see that this silent was broken when Calcutta High Court made a historic judgment that allowed the patent approval to genetically engineered micro-organisms.

In the landmark case of ***Dimminaco AG v Controller of Patents*** [10] the Calcutta High Court on the 15thJanuary, 2002 has provided a landmark decision allowing claim for grant of patent protection to genetically engineered micro-organisms known as infectious bursitis vaccine. The technology used to create a live vaccination that helped prevent infectious bursitis in chicken was the subject of the patent application.

The reason the Patent Authorities denied the proposal was -

i. Making a vaccine using a living organism is not the same as manufacturing.
ii. The aforementioned procedure is not a novel idea [11].
iii. A process covered by an invention must result in a material; therefore, a vaccine that contains a living creature is not considered an invention.

The appellant argued that the communicable bursitis vaccine's creation was an innovation due to:

i. The procedure involves creative phases, and the developed vaccination guards toward infectious tendinitis in chicken.
ii. The registration of a the final result of a procedure that uses live viruses is not prohibited by current Indian law; and
iii. Only the vaccine's true manufacturing is covered by the invention's claim in this instance.

The High Court of Calcutta made the following ruling in relation to the arguments made by both sides:

i. By concluding that the procedure involved is not an invention simply because the final product contains live viruses, the Controller committed a legal error.
ii. The Controller should evaluate the patent claim in accordance with section 3 of the Patent Act. The examiner did not object in accordance with section 3 of the Act.
iii. The vaccination was regarded as a material when the Vendibility Test was used.

The Court has also overturned the Controller's ruling, proving established the Patent Act did not prohibit the registration of patents of biotechnological innovations. The court ordered the Patent office to reexamine the application, citing the dictionary definition of manufacture, which does not prohibit a vendable product containing live beings, because there is no statutory definition of the term. The Controller has given

the microorganism patent protection in accordance with the High Court's ruling. It is argued that this ruling has created new avenues for acquiring patents in India for inventions pertaining to microorganisms that were previously denied. The most significant difference between Indian and developed legal systems, however, is that microorganisms that are already present in nature cannot be patented in India because, according to section 3(d), they are considered discoveries and cannot be patented [12].

6. CONCLUSION

The process of granting patent protection to biotechnology goods is extremely complicated, especially when human beings are involved. Living organisms cannot be created by man, there must be a clear-cut distinction between “invention” and “discovery”. When this distinction between the two cannot possibly be given a clear cut distinction , the process of granting patent to such living organism (micro-organism) becomes a “blackbox” and therefore impossible to describe. In countries where biotechnology patents are permitted, full communication of the innovation is essential for patent protection. The need that the invention be "new" is another issue that makes patenting biotechnology more difficult. This is a technological issue because it rarely creates anything new, as a matter of fact it tries to synthesis the creation of something from a substance that is already existing in nature. Therefore, it is necessary to change the basic essence of the bundle of patent rights worldwide for the purpose for the biotechnology industry to expand.

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