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RESEARCH ARTICLE

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NON - OBVIOUSNESS IN BIOTECHNOLOGY INVENTIONS - AN OVERVIEW

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Manuscript Info

Abstract

"BIOTECHNOLOGY" is the use of biological processes, organisms, or systems to manufacture products intended to improve the quality of human life. Humans have been harnessing biology for thousands of years to make food such as bread and cheese, and medical products derived from plants. Inventors have been filing applications for biotechnology patents for over a hundred years. Biotechnology is an important industrial sector for the European economy, providing employment and growth for European society and countless useful medical and other products for its citizens. Patents are also an effective barrier to illicit copying of medicines and the health risks associated with unauthorised copycat versions. The Patent Act provides no inclusive definition of patentable subject matter, providing only a list of what is considered unpatentable. Unfortunately, these exceptions can be vague, leading sometimes to uncertainty – and this is especially true for biotechnology inventions, due to the complex nature of the technology. Innovators, investors and patent practitioners must analyse their inventions in light of Indian patent law before making any strategic decisions regarding patenting in India. Biotechnology Patent and India. Patent Act in India was enacted in 1856. It has been modified several times since then; one major amendment being in 1970 which satisfied the international norms of patentability covering novelty, inventive step and industrial application. But this version had nothing specific concerning Biotechnology invention and protection. At the same time, since the patent offices and courts in US and EU were seeing increasing number of biotech inventions and patent application, the demand for amendment of Indian Patent Act to introduce biotech patentability gained voice in India. The amendment came in 2002 to explicitly include biochemical, biotechnological and microbiological processes within the definition of potentially patentable process.

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Introduction:-

"Biotechnology can transform humanity provided humanity wishes to be transformed - GEOFFREY CARR.

The development of the genetic resources of biodiversity is known as Biotechnology. Biotechnology inventions are important for human development. It is the broad area of biology involving living systems and organisms to develop or make products, or any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific uses.

A biological patent is a patent on an invention in the field of biology that by law allows the patent holder to exclude others from making, using, selling, or importing the protected invention for a limited period of time. Biotechnology patents fall under the scope of utility patents

The Hungarian Károly Ereky coined the word "biotechnology" in Hungary during 1919 to describe a technology based on converting raw materials into a more useful product.

Under section 18(1) of the Patents Act 1990 (Cth), your biotech invention will be eligible for standard patent protection if it meets the following criteria:

1. It's an invention,
2. It's novel,
3. It involves an inventive step, and
4. It's useful.

If you are filing for an innovation patent, your biotechnology invention must involve an innovative rather than inventive step.

Industrial Applicability

In India, for an invention to be industrially applicable, it is necessary to prove that the invention can be made, Can be used in at least one field of activity and Can be reproduced with the same characteristics as many times as necessary. Since, no specific mention with regard to industrial applicability of biotechnology patents have been provided for in the act, it is reasonable to apply the general industrial applicability standards to biotechnology inventions. If biotechnology inventions can be made and used in an industry and can be reproduced as many times as required, they would satisfy the Industrial Applicability requirement in India. The guidelines for examining biotechnology inventions in the Draft manual of Patent Practice, 2008 provide that gene sequences and DNA sequences whose functions are not disclosed do not satisfy the Industrial Applicability requirement.

Novelty

The Patents Act does not have any explicit provisions with respect to novelty of biotechnology inventions. Since most biotechnology inventions are products of nature inherently present in living organisms, they could be construed as discoveries and not patentable. However, the Draft Manual of patent practice and procedure, 2008 provides that biological material such as recombinant DNA, Plasmids and processes of manufacturing thereof are patentable provided they are produced by substantive human intervention. As there are no decided cases on the subject, the interpretation of the Manual is being used to analyze novelty of biotechnology inventions. Several patents have been granted for isolated gene sequences in India and such sequences have been considered to be novel by the patent office in the light of their natural counterparts.

Inventive Step

Due to dearth of case law, the approach to inventive step with regard to biotechnology inventions in India is not clear. As per the 2008 Draft Manual, it can be safely concluded that isolated gene sequences and protein sequences will be considered to have an inventive step in the light of their naturally existing counter parts. Furthermore, the economic significance requirement is relatively easy to prove for biotechnology inventions due to their various applications in drugs and diagnostics sector. Principles such as reasonable expectation of success, predictability of the field and so on are applied to determine inventive step in India as well and would be applied to biotechnology inventions. However, as it stands now the law does not indicate any differing standards for biotechnology inventions when compared to other inventions.

Enablement

In India, for biotechnology inventions, which describe biological material in the specification, the law provides for deposit of such biological materials at a recognized depository. The manual of patent practice and procedure

requires the invention to be described completely in the specification to enable a person skilled in the art to be able to carry out the invention by reading the specification. However, there are no cases in India that talk about differing written description or enablement standards for biotechnology inventions.

Morality

Section 3(b) of the Indian Patent Act provides that an invention the primary or intended use or commercial exploitation of which would be contrary to public order or morality or which causes serious prejudice to human, animal or plant life or health or to the environment is not patentable. As per the section an invention would not be patentable if it is immoral or against public order, harmful to human, animal or plant life or harmful to environment. The Draft Manual of Patent Procedure, 2010 provides that Any biological material and method of making the same which is capable of causing serious prejudice to human, animal or plant lives or health or to the environment including the use of those that would be contrary to public order and morality are not patentable. It further provides that the processes for cloning human beings or animals, processes for modifying the germ line, genetic identity of human beings or animals, uses of human or animal embryos for any purpose are not patentable as they are against public order and morality. The Indian Patent Law has strong prohibitions against patenting of biotechnology inventions based on morality and public order.

Biotechnology Patent and India:

Patent Act in India was enacted in 1856. It has been modified several times since then; one major amendment being in 1970 which satisfied the international norms of patentability covering novelty, inventive step and industrial application. But this version had nothing specific concerning Biotechnology invention and protection. At the same time, since the patent offices and courts in US and EU were seeing increasing number of biotech inventions and patent application, the demand for amendment of Indian Patent Act to introduce biotech patentability gained voice in India. The amendment came in 2002 to explicitly include biochemical, biotechnological and microbiological processes within the definition of potentially patentable process.

Statutory obstacles to patentability:

The criteria for fulfilling patentability requirements are novelty, inventiveness, and industrial application. Apart from this, some inventions are also excluded from patentability under section 3 of the Patent Act, 1970.

What Is Not Patentable In India:

Section 3 (b) - . As per the section an invention would not be patentable if it is immoral or against public order, harmful to human, animal or plant life or harmful to environment

Discovery of living things or non- living substances in nature - Section 3 (c)

Plants and animals in whole or any parts thereof other than micro-organisms but including seeds, varieties and species - Section 3 (j)

Essentially biological processes for the production or propagation of plants and animals– Section 3 (j)

Any Process for the medicinal, surgical, curative, prophylactic, diagnostic or therapeutic or other treatment of human beings or animals to render them free of disease or to increase their economic value or that of their products – Section 3(i)

Methods of agriculture or horticulture – Section 3(h) Traditional knowledge – Section 3(p)

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.

Biotechnology Inventions

The historical application of biotechnology throughout time is provided below in order. These discoveries, inventions and modifications are evidence of the evolution of biotechnology since before the common era.

Before Common Era

1. 7000 BCE – Chinese discover fermentation through beer making.
2. 6000 BCE – Yogurt and cheese made with lactic acid-producing bacteria by various people.
3. 4000 BCE – Egyptians bake leavened bread using yeast.
4. 500 BCE – Moldy soybean curds used as an antibiotic.
5. 250 BCE – The Greeks practice crop rotation for maximum soil fertility.
6. 100 CE – Chinese use chrysanthemum as a natural insecticide.
7. 1663 – First recorded description of living cells by Robert Hooke.
8. 1677 – Antonie van Leeuwenhoek discovers and describes bacteria and protozoa.
9. 1798 – Edward Jenner uses first viral vaccine to inoculate a child from smallpox.
10. 1802 – The first recorded use of the word biology.
11. 1824 – Henri Dutrochet discovers that tissues are composed of living cells.
12. 1838 – Protein discovered, named and recorded by Gerardus Johannes Mulder and Jöns Jacob Berzelius.
13. 1862 – Louis Pasteur discovers the bacterial origin of fermentation.
14. 1863 – Gregor Mendel discovers the laws of inheritance.
15. 1864 – Antonin Prandtl invents first centrifuge to separate cream from milk.
16. 1869 – Friedrich Miescher identifies DNA in the sperm of a trout.
17. 1871 – Ernst Hoppe-Seyler discovers invertase, which is still used for making artificial sweeteners.
18. 1877 – Robert Koch develops a technique for staining bacteria for identification.
19. 1878 – Walther Flemming discovers chromatin leading to the discovery of chromosomes.
20. 1881 – Louis Pasteur develops vaccines against bacteria that cause cholera and anthrax in chickens.
21. 1885 – Louis Pasteur and Emile Roux develop the first rabies vaccine and use it on Joseph Meister.

20th century"

1. 1919 – Károly Ereky, a Hungarian agricultural engineer, first uses the word biotechnology.[citation needed]
2. 1928 – Alexander Fleming notices that a certain mould could stop the duplication of bacteria, leading to the first antibiotic: penicillin.
3. 1933 – Hybrid corn is commercialized.
4. 1942 – Penicillin is mass-produced in microbes for the first time.
5. 1950 – The first synthetic antibiotic is created.
6. 1951 – Artificial insemination of livestock is accomplished using frozen semen.
7. 1952 – L.V. Radushkevich and V.M. Lukyanovich publish clear images of 50 nanometer diameter tubes made of carbon, in the Soviet Journal of Physical Chemistry.
8. 1953 – James D. Watson and Francis Crick describe the structure of DNA.
9. 1958 – The term bionics is coined by Jack E. Steele.
10. 1964 – The first commercial myoelectric arm is developed by the Central Prosthetic Research Institute of the USSR, and distributed by the Hangar Limb Factory of the UK.
11. 1972 – The DNA composition of chimpanzees and gorillas is discovered to be 99% similar to that of humans.
12. 1973 – Stanley Norman Cohen and Herbert Boyer perform the first successful recombinant DNA experiment, using bacterial genes.
13. 1974 – Scientist invent the first biocement for industrial applications.
14. 1975 – Method for producing monoclonal antibodies developed by Köhler and César Milstein.
15. 1978 – North Carolina scientists Clyde Hutchison and Marshall Edgell show it is possible to introduce specific mutations at specific sites in a DNA molecule.
16. 1980 – The U.S. patent for gene cloning is awarded to Cohen and Boyer.
17. 1982 – Humulin, Genentech's human insulin drug produced by genetically engineered bacteria for the treatment of diabetes, is the first biotech drug to be approved by the Food and Drug Administration.
18. 1983 – The Polymerase Chain Reaction (PCR) technique is conceived.
19. 1990 – First federally approved gene therapy treatment is performed successfully on a young girl who suffered from an immune disorder.
20. 1994 – The United States Food and Drug Administration approves the first GM food: the "FlavrSavr" tomato.

21. 1997 – British scientists, led by Ian Wilmut from the Roslin Institute, report cloning Dolly the sheep using DNA from two adult sheep cells.
22. 1999 – Discovery of the gene responsible for developing cystic fibrosis.
23. 2000 – Completion of a "rough draft" of the human genome in the Human Genome Project.

21st century

1. 2001 – Celera Genomics and the Human Genome Project create a draft of the human genome sequence. It is published by Science and Nature Magazine.
2. 2002 – Rice becomes the first crop to have its genome decoded.
3. 2003 – The Human Genome Project is completed, providing information on the locations and sequence of human genes on all 46 chromosomes.
4. 2008 – Japanese astronomers launch the first Medical Experiment Module called "Kibo", to be used on the International Space Station.
5. 2009 – Cedars-Sinai Heart Institute uses modified SAN heart genes to create the first viral pacemaker in guinea pigs, now known as iSANS.
6. 2012 – Thirty-one-year-old ZacVawter successfully uses a nervous system-controlled bionic leg to climb the Chicago Willis Tower.

Biological patents in different jurisdictions

Australia

In February 2013, Judge Justice John Nicholas ruled in the Federal Court of Australia in favour of a Myriad Genetics patent on the BRCA1 gene. This was a landmark ruling, affirming the validity of patents on naturally occurring DNA sequences. However, the U.S. Supreme Court came to the opposite conclusion only a few months later. The Australian ruling has been appealed to the Full Bench of the Federal Court; submissions in the case include consideration of the U.S. Supreme Court ruling. This decision was decided in 2014, affirming Nicholas J's decision in favor of Myriad, confirming that isolated genetic material (genes) are valid subjects of patents. As of June 2015 the case was pending hearing in the High Court of Australia. In October 2015 the Australian high court ruled that naturally occurring genes cannot be patented.

Europe

European Union directive 98/44/EC (the Biotech Directive) reconciled the legislation of biological patents among certain countries under the jurisdiction of the European Patent Organisation. It allows for the patenting of natural biological products, including gene sequences, as long as they are "isolated from [their] natural environment or produced by means of a technical process."

The European Patent Office has ruled that European patents cannot be granted for processes that involve the destruction of human embryos.

Japan

Under the umbrella of biotechnology, applications for patents on biological inventions are examined according to general guidelines for patents. In response to requests for additional clarity, the Japan Patent Office (JPO) set forth specific guidelines for biology-related inventions. Over the years, the JPO has continued to amend these guidelines to clarify their application to new technologies. These amendments have broadened the scope of patents within the biotechnology industry. The Japanese Patent Act requires that patented inventions be "industrially applicable", i.e. they must have market or commercial potential. The JPO explicitly lists "medical activities" among inventions that fall outside the scope of industrially applicable inventions, meaning that methods of surgery, therapy, and the diagnosis of human diseases cannot be patented.

United States

In the United States, up until 2013 natural biological substances themselves could have been patented (apart from any associated process or usage) if they were sufficiently "isolated" from their naturally occurring states. Prominent historical examples of such patents include those on adrenaline, insulin, vitamin B12, and various genes. A landmark ruling by the U.S. Supreme Court in June 2013 declared naturally occurring DNA sequences ineligible for patents.

What Are the Benefits?

Patentable inventions attract investors to move them to the commercial stage. If you don't take steps to protect your idea, then regardless of its innovation or utility, investors may not want to take such a risk. Patenting biotech provides an incentive for scientific researchers to continue their work.

Major Difficulties :

The major difficulties encountered by biotech firms are, thus, how to collect money, how to find investors and/or how to obtain funding when the risk of not reaching a final valuable product is so high. Moreover, the complexity and slowness of the pathway to obtain such funding are often a hurdle especially for small/medium firms which, by the way, is the case for most biotech entities in Europe.

Intellectual Property can be considered a law system which tries to balance the two situations, i.e. free access and absolute monopoly.

Moral Issues:

It is true that necessity propels any invention. In this new era our necessities are increasing fuelling inventions but again it is our responsibility to protect our rights too.

Organ Transplantation

Organ transplantation is a big moral issue for biological based invention. It possess a big moral issues. The biological invention facilitate the organ transplantation is opposed by numerous intellectual based on religious faith. Also it is anticipated by some that it may give rise to illegal Human trafficking.

Biological Weapons

Biological weapons are the most dreaded ones today, far more dangerous than nuclear, chemical or conventional weapons. Discussion on this issue is most crucial.

Bioinformatics

It is a methodology of biological studies implemented with the help of computer programme. It is generally used for gene identification and prediction of upcoming diseases. Many believe that this could bring legal turmoil in the society. Also it may hamper the natural living of humans.

Time period

The term of every patent granted is 20 years from the date of filing of application. However, for application filed under national phase under Patent Cooperation Treaty(PCT), the term of patent will be 20 years from the international filing date accorded under PCT.

Example of Biotechnology Inventions -***Oil-eating bacteria :**

Plunging down to a depth of about 11,000 m (36,000 ft), the Mariana Trench is the deepest part of the ocean, so it's no surprise that we don't really know what's down there. New species and strange sounds have turned up recently, and now researchers have discovered a new group of oil-eating bacteria.

For the new study, the team collected samples of the microbial population from the deepest part of the trench. After recreating those environmental conditions in the lab, the researchers discovered that some of these bacteria consume hydrocarbons – in fact, it turned out that nowhere on Earth had more hydrocarbon-degrading bacteria than the Mariana Trench.

Conclusion:-

It can be seen that the Biotechnology and life form patentability is a subject of exploration in India. With more and more research and innovation going on in this field and keeping in view the rich bio-diversity that India enjoys, there is a real need to protect the interest of inventors. India needs to enable its inventors and inventions to compete in the global scenario, although few claims are considered but they are more on case-to-case basis and there is a lack of tidy guidelines.