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Legal Framework of Biotechnological Inventions: Issues and Challenges

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Abstract: *Invention distinguishes human life from living world. Purely creation of human mind and brain, inventions have made far reaching developments in human life. Invention is again created from limited resources by human beings. In quest of better life, man has exploited his inventive mind and designed devices for peaceful healthy life. Important innovative branch of human inventions is biotechnological inventions. Industrialization at the end of nineteenth century paved way to mechanization ultimately resulting into new products and processes used in industry. Advancement of genetic science revolutionized biotechnology and new branch of industry engaged in genetic engineering. All inventions are dealt by patents law which expect that inventions are patentable but not discoveries. Therefore, when question came up for patenting of genetically modified microorganisms, it was answered in negative as it was presumed that microorganisms are naturally occurring entities. In Anand Chakrabarty's case US Supreme Court opined that patent protection is available for a micro-organism that is artificially constructed rather than naturally occurring and new arena unlocked for inquisitive human mind. New branch grew to the patents law under IPR blooming industries engaged in genetic engineering ranging from foods to drugs.*

Keywords: IPR, patent, biotechnological inventions, genetic engineering

I. INTRODUCTION

Invention is something that has never been made before; or process of creating something that has been never made before.[1] In other words, inventions are creations of human brain that were not in existence on the earth and form part of world of intellectual property. Man is inquisitive by nature and this inquisition has given rise to inventions besides doubts and necessity. In his quest for excellence, he invented products and processes to smoothen human life and to elongate life he invented drugs and medical treatments. One such attempt of man is biotechnological inventions.

Biotechnological inventions refer to techniques that use leaving organisms or parts of them in order to make or modified products or to improve or modify certain or all the characteristics of plants or animals in order to develop microorganisms and organisms intended for specific uses.[2] The Indian patent office considered biological inventions to be related to living entities of natural origin such as animals human beings including parts there of living entities of artificial origin such as microorganisms vaccines transgenic animals and plants biological materials such as DNA plasmids jeans vector tissues sales replicons process relating to leaving entities processes relating to biological material methods of treatment of human or animal body biological processes or essentially biological process.[3]

Biotechnological inventions" are inventions which concern a product consisting of or containing biological material or a process by means of which biological material is produced, processed or used.[4]

[1]https://dictionary.cambridge.org/us/dictionary/english/invention accessed on 31/12/2024
[2]https://www.glp.eu/en/resources/focus/patents/biotechnological-inventions/ accessed on 1/1/2025
[3]Chawala H.S. (2005). Patenting of Biological Material and Biotechnology. *Journal of Intellectual Property Rights,* (10). 44-51
[4] https://www.epo.org/en/legal/epc/2020/r26.html

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Importance of Biotechnological Inventions

The European Parliament and the Council of The European Union laid down the need and importance of legal protection of biotechnological inventions-

Biotechnology and genetic engineering are playing and increasingly vital role in wide ranging industries. Protection of biotechnological inventions shall be essentially important for industrial development. India stands among first 12th top biotechnological industries that can manifest its economic reach comprising around 5000 companies. Similarly large number of private and public research institutions are engaged in research and development in biotechnological industries. This requires huge amount of money or capital and enormous time for research and development. The huge investment of labour and capital needs to be given statutory protection by grant of patent to biotechnological inventions. By technological industry is blooming all over the world including India. Protection of biotechnological inventions shall be crucial in protecting creation and efforts of the biotechnological industries leading to employment generation and encouragement to investors.

Field of genetic engineering and its research and development required considerable amount of high-risk investment. Its adequate legal protection can make them profitable. Industries engaged in biotechnological inventions are required to invest huge amounts in research and development. As compared to other industries, these industries are expected to spend huge amounts on hygiene and sanitation which is an extra burden on capital. Small mistakes cause huge losses resulting into multiple experiments and this is another burden on the capital.Since biotechnological inventions are closely associated with human life, future unforeseen risks also needs to be attended cautiously. Experiments is that create burden on capital as compare to other industries. The industries to compensate the capital investment through royalty.

Development of biotechnology is important to developing countries in combating health issues epidemics and endemic diseases. This also assists in addressing issues of hunger in the third world. Human life span has increased due to advanced medications and medicinal treatments full stop when important source of medical medicines medications and drugs is biotechnological inventions. Biotechnological inventions play an important role in human life and eradication of cowpox, polio could be possible only with the help of biotechnological inventions. Similarly making these biotechnological inventions at cheaper rate has played vital role in increasing human life specially in developing and undeveloped country. Biotechnological inventions also involve engagement of people and capital for development of human life.

Legal Framework for Patents-

Intellectual property rights are broadly classified as literary and industrial inventions. Industrial inventions comprises patents, trademarks, industrial designs, integrated circuits, etc. The word patent has come from Latin language, from word '*patene'* meaning to open. Patent, legally means monopoly rights granted to an inventor for disclosing his invention in the form of specification. Patent grants exclusive rights to the inventor to use, sell and manufacture the inventions. Unlike copyright, patent rights cannot be claimed before its grant by authority and for grant of patent, as invention needs to pass the criteria of patentability[5]. For grant of patent. An invention shall be new, having inventive step and industrial applicability.

Even though new, comprises inventive step and industrial applicability, care must be taken that an invention shall not fall into category of non-patentable inventions. Non-patentable inventions comprise inventions against public morality, public health, things already on earth, scientific principles, etc.

Patentability and Biotechnological Inventions-

All inventions are not capable of grant of patent. Section 3 & 4 of the Patents Act, 1970 deal with patentability of inventions. According to section 3, for grant of patent, there must be an invention; and such invention must be new or novel. Such invention shall not be obvious and shall be useful industrially.

[5]S. 3 The Patents Act, 1970

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Invention

An invention is creation of intellect, applied to capital and labour to produce something new and useful. Section 2(1) (j) defines invention as a new product or process involving inventive step and capable of industrial application. Thus, invention may be a product or process. Invention means something new which was not in existence or known before it was made. An invention is said to be publicized if it is known prior to patenting. A patent can be granted if it is an invention.

According to section 2(1) (l) new invention means any invention or technology which has not been anticipated by publication in any document or used anywhere in the world before the date of filing of complete specification of patent application. An invention must be new or novel and result in new product or process. It shall also involve an inventive step and would be capable of industrial application.

Inventive Step

Inventive step means a feature of an invention that involves technological advances as compared to the existing knowledge. An invention having economic significance also is considered as invention capable of patent. Thus, an inventive step involves either technological advancement or economic significance. Generally, an invention must be new for patentability but to this rule, the Patent Amendment Act, 2005 has created an exception. Even if there is technical advancement as compared to the existing knowledge or economic significance or both, an inventive step involving simply technological advancement is patentable. Similarly, a person can also get a patent if inventive step is economically significant

Novelty

Invention must be new or novel. It means on the date of filing of patent application, it should not form part of state of prior art. 'State of prior art' means that the matter was made available to the public before the priority date of invention i.e. the matter was known to the public by written or oral description or by used or by any other way. Thus, an invention should not be found in any matter whether as a product or process or information.

The fundamental principle of patent law is that a patent is granted only for an invention which must be new and useful i.e. it must be novel and useful. It is essential for the validity of patent that it must be the inventor's own discovery. Prior public knowledge of the alleged invention would disqualify the grant of patent.

Non obvious

In addition to novelty, patentability also requires non-obvious nature of the subject matter sought to be patented. Sometimes some inventive is done for the first time which is result of addition of a new idea to the existing stock of knowledge. Patent is not to be granted for every trivial advancement. Minor improvements are considered as work of a skilful mechanic for which protection ought not be granted. But simplicity of invention is not the criteria of non obviousness.

In *Graham vs. John Deere Company*,[6] laid down certain factors to be considered to find out whether invention was obvious or non-obvious:

1. The scope and content of prior art-Prior art means the knowledge existing in public domain e.g. existing technologies.
2. The difference between the prior art and the claims at issue i.e. to see what is the difference between the existing technology and the claimed invention.
3. The level of ordinary skill in the pertinent act-

Besides this, the court can also consider

- commercial success of claimed invention;
- long felt but unsolved needs;
- the failure of others to solve the problem.

[6]383 U.S. 1 (1966)

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Obvious is judged by viewing the invention as a whole.

Industrial applicability

It means the invention must be capable of being manufactured or used in an industry. The invention must also be useful. However, in some countries such 'not so useful' inventions are protected as 'utility models.'

Patenting Biotechnological Inventions- Issues:

Since living things and non-living substances on earth are not patentable, patenting biotechnological inventions walked long distance. Intellectual property refers to creation of human mind and brain that is there must be investment of human labour or skill to claim right as property over creation. Question popped up when patent was claimed for biotechnological inventions, whether these inventions fir into the criteria of patentability. Biotechnological inventions are human mutated or accentuated inventions. The recombinant DNA technology has made possible for the human beings to mutate artificially DNA and bring expected or predetermined characteristics in living things such as plants, micro-organisms.

A claim to a product obtained or produced by a process is anticipated by any prior disclosure of that particular product per se regardless of its method of production is called product-by-process claims, for example method of production a polypeptide or compound or a transgenic microorganism or a plasmid.[7]

Biotechnology deals with living things and involves alteration of genomic materials of an organism. Such alteration may have a deep impact upon the environment or the human animal or plant life involving serious questions about morality. Hence adequate care should be taken while examining the inventions and care shall be taken that the final product shall not be contrary to public order, morality or causing serious peril to living beings or health or to the environment.

A process of cloning human beings or animals or a process for altering the germ line of human beings or a process for modifying the genetic identity of animals which are likely to cause them suffer. However, patenting may be given second thought if there is substantial medical or other benefit to man or animal due to such process. Similarly, a process for preparing seeds or other genetic materials comprising elements which might cause adverse environmental impact or uses of human embryo's for commercial exploitation shall not be granted patent.

Legal Development of Patenting of Biotechnological Inventions-

TRIPS made provisions for patentability of inventions under Article 27 and excluded certain inventions from arena of patentability. It excludes plants, animals otherthan micro-organisms but includes impliedly non-biological

Regarding biotechnological products, historically till 1980 no patent was granted on living beings anywhere in the world. In 1948 in Funk Brothers Seed Company vs. Carlo Inc. the US Supreme Court refused to grant patent on non-natural seeds. Further in 1976 the German Supreme Court in Red Dove case also refused to grant patent on non-natural living things. For the first time in 1980 in Diamond vs. Anand Chakravarthy, the US Supreme Court granted a patent on microorganisms that is a non-natural or genetically modified bacteria which was capable of performing certain non-natural functions of eating and cleaning up oil spills and that non-natural living beings are covered under the phrase composition of matter and is patentable.

Considering this decision of the US Supreme Court apatent was granted by a European court in Genetic-I or polypeptide expression on plasmid, a microorganism genetically modified to express foreign proteins. The European court held that under the European Patent Convention, 1977 naturally produced living beings such as plants, animals and microorganisms are non-patentable. In 1980, patent was granted in the landmark case of Anand Chakrabarty. Subsequently in 1990 Harvard/Oncomouse case the patent was granted by US Patent office on Oncomouse a non-natural animal genetically mutated to become susceptible to cancer, useful in Cancer research. Subsequently, US patent office also granted on Oncomouse.These decisions encouraged the granting of patent to non-natural plants. In John Moore case patent was granted on the cell lines of human beingsuseful in producing cancer fighting proteins. In HarvardFlorey case patent was granted by European patent office for the genetic engineered DNA from a pregnant

[7] Guidelines for Examination of Biotechnological Applications for Patent, 2013; 5

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women's body to produce a human H2 Relaxin.InNovartis case it was made clear that DNA, RNA and human cells could be patented. In 1994 in the case of Pioneer Hybrid International vs.Golden Foundation Seeds Inc. the Supreme Court clearly laid down that human cloning and human being is not patentable[8].

Legal Framework for Biotechnological Inventions-Challenges:

Present legal framework some countries prohibit patenting of medicines, treatments of human and animals while some countries permit it. Medical tourism is patent example of impact of patenting of medicines and treatments. Even citizens of developed countries prefer to approach countries where medicines and treatments are cheaper than developed countries. One such cost of medical field is patent. This ultimately affects the industries engaged in biotechnological inventions.

Patenting of biotechnological inventions has hidden threats. Theory is put forth that COVID-19 virus was manufactured in laboratories, even if considered as untrue, one can see its ill effects not only on health, but also on society, economy, family, etc. As such there is no control on laboratories that are engaged in research of biotechnological inventions. Present legal framework shall bring the laboratories under the rheostat of national as well as international regimes making them mandatory to disclose their areas of research in biotechnological inventions regularly. Shouldering responsibility for mishaps shall also be fixed on such laboratories to regulate their functioning.

II. CONCLUSION

There is mythological story that Rishi Vishwamitra created heaven and worried by his capabilities, God stopped him from completing the making of heaven. If it is accepted as true, we can say that humanmind or intellect has no boundaries and it can think and bring into existence things not thought before. For this, human beings are required to recognize and award these inventions so that they are encouraged to proceed farther as well as others to step into the shoes of such inventors. At the same time, it shall not be forgotten that the human mind needs external control so as to make them understand their boundaries through legal framework. Inventions are double-edged weapons, if not handled carefully, may injure its bearer. Hence, control is essential. Present legal framework plays the same role in existing situation. By encouraging biotechnological inventions, it soothes human life and by prohibiting cloning of human beings, it controls the population, human rights issues, personal issues of human beings.

[8] Jyoti Rattan, Biotechnological Inventions and Patent Law: National and International Perspective, Journal of Post Graduate Medicine, Education and Research, July-September 2016 50(3), 132-135