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# Biological patent and patentability

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## ABSTRACT

Development in the field of Biological patent sprouted a new world in biotechnology, which permits scientist to alter natural biological matter for commercial profit. In response to Scientific Breakthrough in biotechnology, the innovative technologies, demand of capitalist market place and patent law has expanded to accommodate a range of biological inventions. There is always a controversial concept and views whether gene patenting have a positive impact upon research and development, health care and the protection of the environment or not. So, the applicability of patent of substance and process of natural origin is always a topic of discussion or debate which may have either of the faces. The scope and reach of biological patents vary among Jurisdictions. Beside all this, this article provides some glimpses of basic Knowledge of biological patents with their need, types and few landmark examples.

*Keywords: Biological Patent, Need, Development, Scope, types patentability*

## Introduction

Today biotechnology industries are treated as the innovation factory because of its diversity. If innovation occurred in the field of biology then law allows the inventor to debar the others from making, using, selling, or importing the protected invention for a limited period of time then comes under the roof of Biological Patent. Biological patents are poorly understood aspects of modern IP. Still Biotechnology has made rapid progress in the last few decades and this has allowed scientists, academicians and researchers to alter natural biological matter for commercialization in research and development and scientific era.

## Need of patenting innovations

In Francis Galton[1] words, "*In science the credit goes to the man who convinces the world, not to the man to whom the idea first occurs.*" Therefore, it is very important aspect of any research and discovery to communicate and disclose the results to right audiences.

There is an interesting case of Dr. Jerome Horwitz, who synthesized AZT in 1964 as potential anticancer drug with an idea to trick cancerous cell's DNA mechanism and keep cancer cells from duplicating.[2] The idea did not work as expected, and Dr. Horwitz did not patent these nucleoside analogues or the process. In 1984, GlaxoSmithKline patented AZT as a highly successful anti-HIV drug (peak sales of US$700M). But neither Dr Horwitz nor his university ever saw a penny.[3] Therefore, patenting of any innovation, new knowledge, product, method or technology developed regardless of its current use and failure should be patented. It took 20 years to a failed anticancer drug AZT to become a remarkable successful anti-HIV drug AZT.

The intellectual property (IP) is the properties created by the human intellect and are intangible property (or **incorporeal property**, something which a individual or corporation can have ownership of and can transfer ownership to another person or corporation, but has no physical substance). These intellectual properties are further classified into various forms like patent, copyright, trademark, design, geographical indications etc. Out of these various IPs, the most and important type of intellectual property is patent protection. The patent protection gives the monopolized rights over the invention which is novel, non-obvious and has industrial applications. Patents were actually designed as a trade-off between a person who invented it and the person or society who wanted to use it. In continuation the monopoly is granted to the inventor in order to promote the common good. In this article we consider some of the more typical and complex issues related to the field of biological patents and these issues arise because of the nature of the object sought to be patented (such as living organisms).

In the early era of patent laws, the patenting of living organisms was not patentable,[4,5] living organisms have been excluded from the sphere of patentable subject matter because they were treated as the products of nature. With the advent of the biotechnology and its related inventions, wherein the human intervention in the living organisms by applying science and technology as created a new product or process, which not only made the organisms more beneficial but also industrialized the biological process.

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## Biological Patent and patentability

By definition, "*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*."

Biological patent can be obtained on animals, humans and crops. The patenting of each of these has varying implications. Opponents to the patenting of living organism's base their arguments on multiple grounds, citing different ethical, scientific, social and economic reasons.[6]

In continuation of invention in the field of biology, the biotechnology industries are treated as the next big era of the revolution. Biotechnology is very diverse field and divided into various sub fields. Though there is a common concept running through all of them, each sub-field has different characteristics and features therefore general rules cannot be framed for biotechnology as a whole. For example, the branch of molecular biology concerned with the structure, function, evolution, and mapping of genomes is differently treated in biological patent rules as compared to the products and process in an artificial medium of cells derived from living tissue. Further again the plant Tissue culture have different characteristics, application, process and products when compared to animal tissue. Therefore, it is very tough challenge to the Law and authorities to make a general rule for biotechnology as a whole.

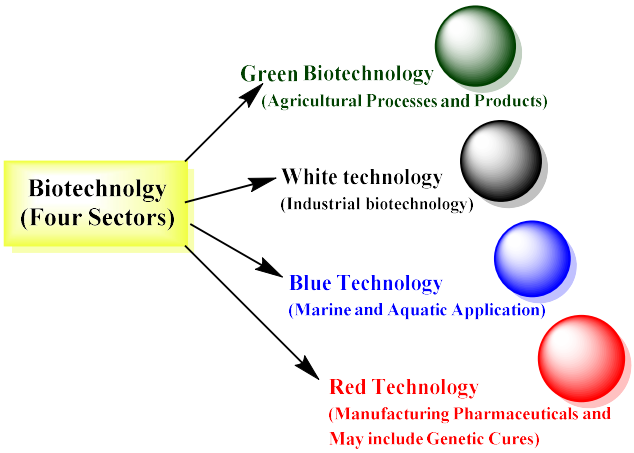


**Figure 1**: Various sectors of biotechnology

## Types of Biotechnology with Reference to Patentable Matter:

Biotechnology is simple technology based on biology, especially when used in agriculture, food science, and medicine (Figure 1). There are four sectors of biotechnology White biotechnology, Green Biotechnology, Red Biotechnology and Blue Biotechnology. Brief information includes that Industrial and other production processes are included in the sector White biotechnology (industrial biotechnology). For example: Enzymes in washing powder,[7] enzymes in chemical production. Similarly, Agricultural processes and products (seed) are included in the Green biotechnology.[8] Examples: Insect-resistant maize; marker-assisted breeding; If it is related with manufacturing of pharmaceuticals like enzymes, antibiotics and vaccines, and its use for molecular diagnostic then it comes under the sector Red biotechnology. In the future this sector may include genetic cures and Bioinformatics. Examples: Vaccines and molecular diagnostic (BRCA1); Finally, Blue biotechnology Sector includes all the marine and aquatic applications. Examples: Cold-water salmon.

In view of the patentability in IPR era the applicant for a patent must demonstrate novelty, utility or usefulness and non-obviousness. An important distinction exists in patent law between discoveries, which are not patentable, and inventions. In contrast to commodity patents, biological patents have many ethical and social impact.

Patenting of Genetic material DNA and **gene** containing a particular set of instructions, usually coding or sequencing is a broad term that refers to the patenting of a process that involves identification, isolation of DNA or associated materials like RNA as well as chemical substances related to DNA such as nucleotides, proteins, and peptides. The genetic materials that can be patented are Genes, DNA Sequences, cDNA. ESTs and SNPs. Following are explained in brief:

**A. Genes:** Genes are known as the basic physical and functional unit of heredity and the working subunits of DNA. They also act as instructions to make molecules called proteins. In humans, *genes* vary in size from a few hundred DNA bases to more than Two million bases. Gene patenting indicates a patent on a specific isolated gene sequence, its chemical composition, processes for obtaining or using it, or a combination of such claims.

**B. DNA sequences:** It includes the process of determining the precise order of nucleotides within a DNA molecule. It involves the method or technology that is used to determine the precise order of nucleotide bases i.e. adenine, guanine, cytosine, and thymine in a strand of DNA.

**C. cDNA (Complementary DNA):** cDNA is synthesized from mature single stranded mRNA by using naturally occurring enzyme (in retrovirus) reverse transcriptase and the resultant cDNA contains exons, with no introns.

**D. ESTs (Expressed Sequence Tags)** In genetics, an **expressed sequence tag** (**EST**) is a short sub-sequence of a cDNA sequence and

**E. SNPs (Single Nucleotide Polymorphs).** is a variation in a single nucleotide that occurs at a specific position in the genome (the complete set of genes or genetic material present in a cell), where each variation is present to some appreciable degree within a population

Genetic materials such as genes, DNA Sequences, cDNA (typically in bioinformatics context), ESTs and SNPs have a variety of applications. In many cases, there are known uses of DNA (vital for the living things), like coding for proteins or diagnostics or in forensic sciences (DNA finger printing, crime scene, paternity etc). However, there are also increasingly innovative uses for DNA, like the sensor developed by researchers at the University of Illinois at Urbana-Champaign have developed DNA sensors that can be used with commercially available personal glucose meters to detect and quantify compounds other than glucose.[9] There is also another research developed by the same university that can detect lead using specially designed DNA. Protein production is one of the most obvious uses of gene sequences, since DNA (carries the information that code for the protein sequence) is the genetic instruction guide for life and its process. These proteins may be structural proteins, hormones, enzymes, blood factors, antibodies, vaccines, or antigens. The gene sequence carrying the information is cloned into a relevant host organism, and the organism is induced to produce the protein.

Patented **Recombinant DNA** technology has **applications** in health and nutrition. This technology allows researchers to insert the individual genes into the genome of other organism for example production of human-insulin growth factor.[10]

Recombinant DNA, patented in the 1970s, was one of the first patents to be obtained on a biological invention. The first licensed drug generated using recombinant DNA technology was human insulin.

## Patents on microorganism

In 1980, in the case of Diamond v. Chakrabarty, the U.S. Supreme Court established the patentability of living matter, provided it was truly 'man-made'. After this decision whole-scale living organisms were permitted to be patented. Since then, companies, organizations, or institutions like the University of California, have patented entire genomes.

The very traditional approach of patent laws were not aware of patenting of Living Organism but by the advent of the biotechnology and biological inventions for human welfare the laws shifted its focus from its primitive site to the current era protection only after late 1980's when in Diamond v. Chakrabarty, first time the protection of microorganism were allowed both in International regime and national regime.[11]

Further there are frequent efforts become speedy to align all national legislations to the set global standards and TRIPS (Trade-Related Aspects of Intellectual Property Rights) is one such convention and also the global efforts are initiated to make the process of filing patent application at one stop platform and analyzing it at global set standard, PCT (Patent Cooperative treaty) is one such convention.

Similarly, in 1988, the Harvard Oncomouse (from the Greek word for tumor) became the first animal to be considered an invention by the United States Patent and Trademark Office ("the USPTO"). The mouse engineered for increased susceptibility to cancer was invented for cancer research. The Harvard Oncomouse patent established the procedure for patenting genetically modified animals. In 1998, primate and human embryonic stem cells were also issued patents by the UPTO.

## Patents on human life

The BRCA Case also highlights the importance of acceptability of gene patents to the general public. Myriad Genetics, Inc. is an American molecular diagnostic company based in Salt Lake City, Utah, United States. Myriad's discovery of the breast cancer gene, BRCA1 was universally acclaimed as a monumental achievement: "There is no more exciting story in medical science." Myriad was the subject of scrutiny after it became involved in a lawsuit over its patenting practices,[11–17] which led to the landmark Supreme Court decision Association for Molecular Pathology v. Myriad Genetics, Inc. The BRCA gene patents have been subject to great scrutiny and opposition in this scenario. BRCA stands for BReast CAncer susceptibility gene. There are two BRCA genes: BRCA1 and BRCA2. By 2003 EPO (European Patent Office) had granted four patents to Myriad Genetics, covering both the BRCA1 and BRCA2 genes. First Patent (EP0699754) covered methods of diagnosis, Second Patent (EP0705903), covered specific mutations of the BRCA 1 gene and Third, (EP0705902) covered the gene itself, the protein and possible diagnostic kits, and Fourth Patent (EP0785216) on the BRCA2 gene, covered not only the sequence of the gene but also use of this information diagnosis, risk prediction, screening or therapy.[17] A standard patent can be obtained for following;

1. Isolated bacteria,
2. Cell lines,
3. Hybridomas related biological materials and their use,
4. Genetically manipulated organisms.

## International regime and national regime (Legislation):

Further in continuation, there is a brief overview of some convention, treaty and agreement related with biological patent: First significant treaty in the International Sphere dealing with the patent right is the Patent Cooperation Treaty. India became a member of PCT (Patent Cooperation Treaty) in 1998. TRIPS (Agreement on Trade-Related Aspects of Intellectual Property Rights): TRIPS agreement came into existence, which added significant value and established high standards. This agreement came into effect on 1 January 1995. TRIPS agreement has three basic features standards, enforcement and dispute settlement. Article 27 of TRIPS deals with the Patentable Subject matter wherein it states Subject to the provisions of paragraphs 2 and 3 of Article 27, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. However, the Paragraph 2 of Article 27 allows the member countries to exclude any inventions if the same is for the purpose of ordre public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law. It further grants liberty to the member countries under paragraph 3 of Article-27 to exclude inventions relating to diagnostic, therapeutic and surgical methods for the treatment of humans or animals; plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. Further it obligates the member countries to Provide protection for plant varieties either by patents or by an effective sui generis system or by any combination thereof. From the careful reading of Article 27(3)(b) specifically says that the microorganisms are the patentable Subject matter and Article 27 gives flexibility of not allowing the Patentability of higher organisms, whether plant or animals and "essentially biological processes for the production of plants or animals and mandates the member countries to give protection for plant varieties either by patents or by an effective 'Sui Generis' system or by any combination thereof. This provision is the key provisions for the granting of patent protection to the Living Organisms but with flexibility of not protecting the higher organisms. In the Uruguay Round of the General Agreement for Trade and Tariffs (GATT) to include IPRs (intellectual property rights) in trade treaties, where patent on life were included. Most of the industries drafted and pushed Trade related intellectual property rights agreements (TRIPs). The TRIPs agreement of GATT (General Agreement on Tariffs and Trade) which is an is an international trade treaty, by allowing for monopolistic control of life forms, has serious ramifications for biodiversity conservation and the environment.

**Table 1** Protection of microorganism in International regime and national regime with different criteria

| Name of countries | Are plants Protectable | If Yes: Are there restrictions? | Are plants cells or parts patentable | Are Plant seeds Protectable | Are DNA sequences patentable? | If Yes: Are there restrictions |
|---|---|---|---|---|---|---|
| AR | NO | - | NO | NO | YES | Only non-natural sequences |
| AU | YES | Inventive steps | YES | YES | YES | NO |
| BR | NO | - | NO | NO | YES | Only non-natural sequences |
| CA | NO | - | YES | NO | YES | NO |
| CL | NO | - | NO | NO | YES | Only non-natural sequences |
| CN | NO | - | YES | NO | YES | NO |
| EC | YES | Inventive steps; no varieties | YES | YES | YES | NO |
| US | YES | Non-obviousness | YES | YES | YES | NO |

AR(Argentina), AU(Australia), BR( Brasil), CA(Canada), CL( Chile),CN( China), EC (European Countries), US (United States of America).

The provision of Paragraph 2 of Article 27 shall be reviewed four years after the entry into force of the Agreement establishing the WTO (World Trade Organization). While most Third World countries wanted TRIPs changed to prevent patents on life and biopiracy, the US is upholding the patenting of life forms and indigenous knowledge. Another one is Budapest Treaty.[18,19,20] Budapest Treaty is signed in Budapest, Hungary, on April 28, 1977 on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure. It entered into force on August 9, 1980, it was later amended on September 26, 1980. India becomes a signatory from 2001.The treaty is administered by the World Intellectual Property Organization (WIPO). The treaty allows "*deposits of microorganisms at an international depositary authority to be recognized for the purposes of patent procedure*". In India, there are two international depositaries situated in Institute of Microbial Technology, Chandigarh and Microbial Culture Collection, Pune. The period of storage of deposited micro-organism may be 30 years or 5 years after the most recent request of sample, whichever is earlier. The treaty doesn't define the meaning of micro-organism but the range of materials able to be deposited under the Budapest treaty includes – Cells (Bacteria, fungi, eukaryotic cells lines, plant sores); Genetic vectors (plasmids or bacteriophage vectors or viruses), Purified nucleic acids. The protection of Living Organisms is topic of debate and the decision, clause and criteria varied from one jurisdiction to another jurisdiction. For example, in US a liberal approach is adopted in granting patents whereas in Europe the approach of granting Patents to living organisms are much conservative. But all over the world, the view of restrictions specifically with regard to moral and ethical grounds are admissible. However, the Indian position differs mostly when compared to the US and Europe. In India except microorganism no other forms or higher forms of living organisms are allowed for patent protection. Even the methods and process involving living organism like microorganisms for the purpose of medicinal, surgical, curative, prophylactic (diagnostic, therapeutic) or other treatment of human beings or any process for a similar treatment of animals to render them free of disease or to increase their economic value or that of their products are not allowed for patent protection. The plant varieties are exclusively kept out of the purview of the patent Act and granted a sue-generis protection for such varieties. Protection of microorganism were allowed both in International regime and national regime with different criteria. Some questions related with biological patents with different countries are depicted in table – 1. The prospects of Indian position in IPR reflects that there is need to improve stewardship of IPR and find some new alternative solutions to compete with the ethical and social issues. Figure – 2 lists patentable and non-patentable biologicals in India based on Indian patent act 1970 and amendments.

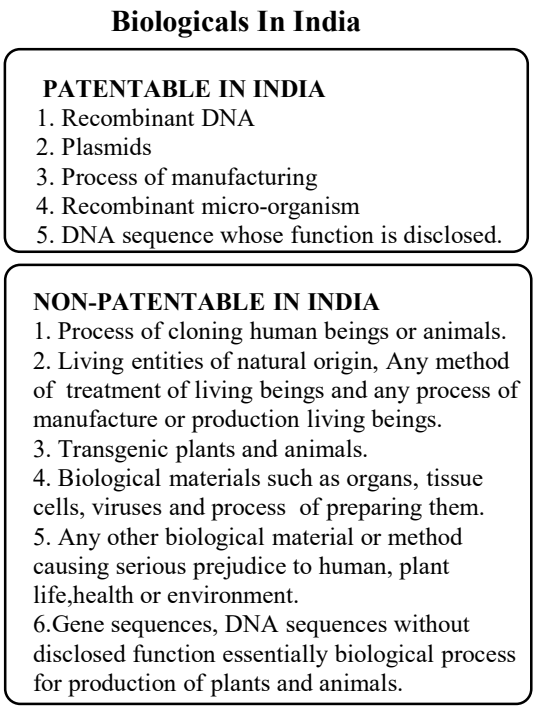


**Figure 2** Patentability of biologicals in India

## National legislations: Indian position:

The Indian Patent Act Specifically bars certain inventions involving Living organisms from the criteria of Patentability. Section 3 of the Act specifically lays down what are all not the inventions like a method of agriculture or horticulture; any process for the medicinal, surgical, curative, prophylactic [diagnostic, therapeutic] or other treatment of human beings or any process for a similar treatment of animals to render them free of disease or to increase their economic value or that of their products; plants and animals in whole or any part thereof other than micro-organisms but including seeds, varieties and species and essentially biological processes for production or propagation of plants and animals.

The Patent rights are territorial in nature and India grants patent rights only within the Indian Territory and not outside. *The three basic requirements for an invention under Indian law are: (i) novelty:* It should be new (Section 2(1)(j)); *(ii)*

*non-obviousness of the invention*: It should involve an inventive step; and *(iii)* It should be capable of industrial application. Other concepts are Sufficiency of Disclosure and Ordre Public and Morality.

## A landmark decision of India

Dimminaco A. G filed a process patent of preparing infectious Bursitis vaccine. The application was rejected by the Patent Office. The office rejected the application on the grounds that the invention is a living organism. In 2002 Kolkata High Court ruled out the rejection and directed re-examinations of the application and granted patent for the invention involving microorganism. This was a landmark decision in biotechnology.[21.] Below Pie chart represents the distribution of biotechnology related patents in India (Figure 3).

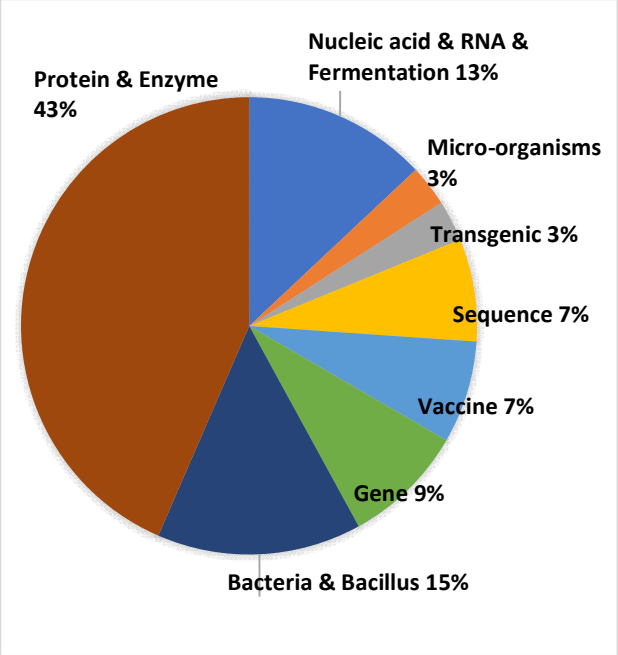


**Figure 3**: Distribution of Biotechnology related patents in India (1999-2003)

Finally, compilation of some examples of biological patents with reference to microorganism related process and Gene related patents granted in India:

**Microorganism related process**

1. A Process for the isolation and accumulation of bacteria for lignin degradation **374/DEL/03**
2. Lactic acid bacteria capable of reducing an individual's tendency to develop allergic reactions **00404/CHENP/2003**
3. Bio power micronized compound from the active principles of inactivated soil beneficial bacteria fortified with blue green algae for improving soil condition to mobilize nutrients for absorption of plant **1096/MUM/2002**
4. Modification of bacteria **IN/PCT/2002/01972/CHE**
5. Expression of an antimicrobial peptide via the plastid genome to control phytopathogenic bacteria **IN/PCT/2002/01370**
6. Beverages contains live lactic bacteria **IN/PCT/2002/01087**

**Some examples of Gene related Patents in India**

1. A method for producing a vector for introducing a desired gene into a plant **358/MAS/2003**
2. A method for producing a vector for introducing a desired gene into a plant **00594/DELNP/2003**
3. Method for accumulating foreign gene product at a high level in plant seeds **00300/CHENP/2003**
4. A method of detection of SPA2 gene variants useful for prediction of predisposition **OTO aspergillus 44/MAS/2003**
5. Gene encoding protein exhibiting agarase activity obtained from an Indian soil isolate **00160/CHENP/2003**
6. A novel gene OSISAP I or RICE and a method of introducing stress tolerances in plant systems using the gene **OSISAP I 1317/DEL/2002a**
7. The Characterization of HUP B gene encoding histone like protein of mycobacterial tuberculosis **1274/DEL/2002**
8. Novel enzyme and the gene encoding the enzyme **IN/PCT/2002/01387**

Gene patenting is a legally contested area in a variety of genetic sciences. The patenting of biological patents (included animals, humans and crops) has varying implications. Opponents to the patenting of living organism base their argument on multiple grounds, citing ethical reasons, scientific reasons and socio-economic reasons.

## Conclusions

It is believed that there is an ongoing process of harmonization of biological patent law throughout the world. Yet, it has its own limitations especially in developing and least developed countries. The biological patent always faces a pressure from ethical, scientific and socio-economic aspect. The patenting of biological patents (included animals, humans and crops) has varying implications.


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