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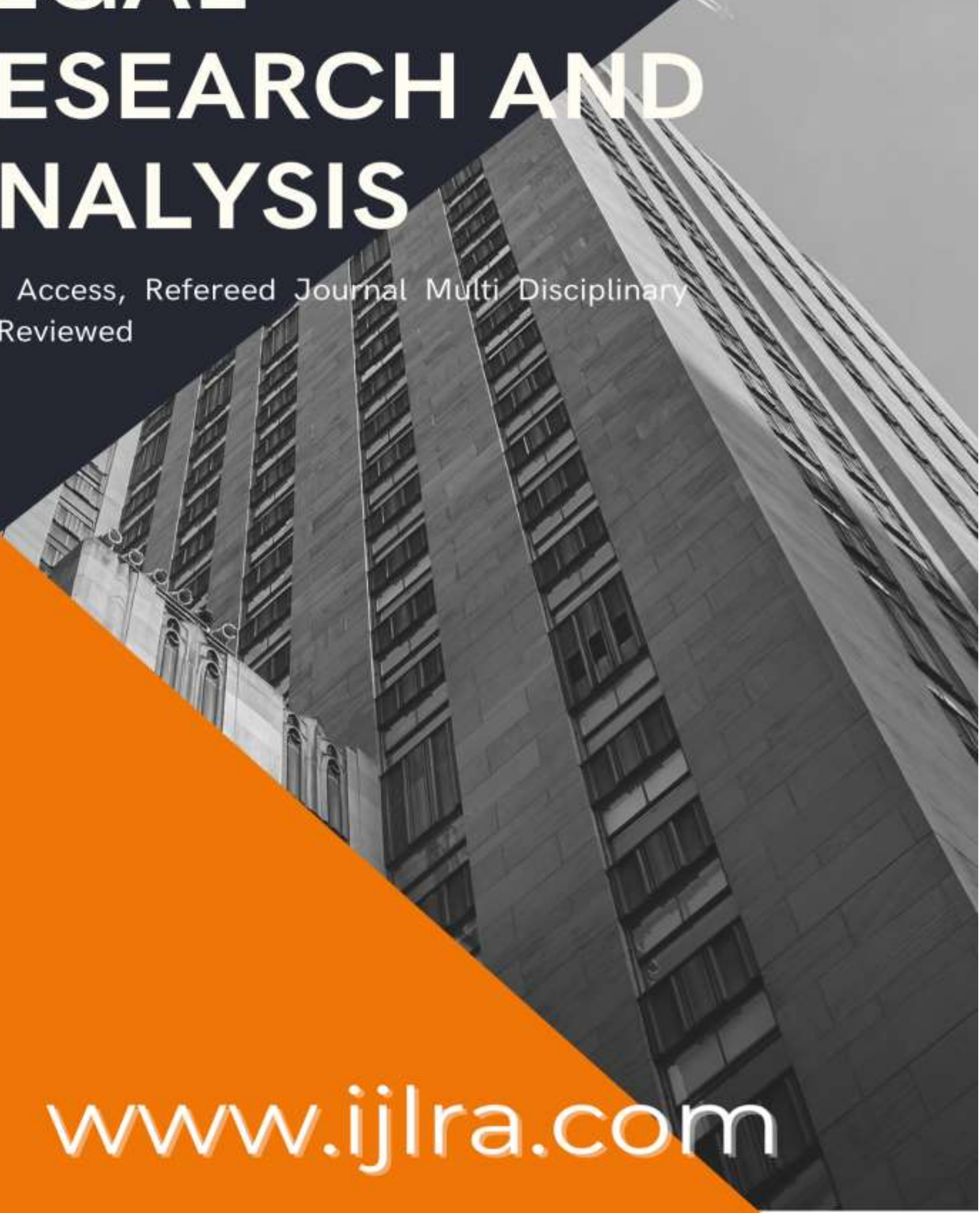

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ORIGIN AND DEVELOPMENT OF BIOTECHNOLOGY

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1) Abstract

Biotechnology is multidisciplinary field which has major impact on our lives. The technology is known since years which involve working with cells or cell-derived molecules for various applications. It has wide range of uses and is termed “technology of hope” which impact human health, well being of other life forms and our environment. It has revolutionized diagnostics and therapeutics; however, the major challenges to the human beings have been threats posed by deadly virus infections as avian flu, Chikungunya, Ebola, Influenza A, SARS, West Nile, and the latest Zika virus. Personalized medicine is increasingly recognized in healthcare system. In this chapter, the readers would understand the applications of biotechnology in human health care system. It has also impacted the environment which is loaded by toxic compounds due to human industrialization and urbanization. Bioremediation process utilizes use of natural or recombinant organisms for the cleanup of environmental toxic pollutants. The development of insect and pest resistant crops and herbicide tolerant crops has greatly reduced the environmental load of toxic insecticides and pesticides. The increase in crop productivity for solving world food and feed problem is addressed in agricultural biotechnology. The technological advancements have focused on development of alternate, renewable, and sustainable energy sources for production of befouled. Marine biotechnology explores the products which can be obtained from aquatic organisms. As with every research area, the field of biotechnology is associated with many ethical issues and unseen fears. These are important in defining laws governing the feasibility and approval for the conduct of particular research.

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2) Introduction

The biotech sector market in India was $420 million during 2002-03. Nearly 70 per cent of this was accounted for by the bio-Parma sector[1]. As far as the remaining components were concerned, 13 per cent was accounted for by the bio-industrial sector, 7 per cent by the bio-services sector (which covers clinical research and related contracted research programmes) and 6 per cent by the agricultural sectors[2]. Bio-safety regulations in India comprise bio-safety rules and guidelines. The existing legislative framework in India for bio-safety regulations has followed a disaggregated approach with regulatory powers imposed in a top-down fashion. The framework legislation for bio-safety regulations in India is the Environment Protection Act. Three provisions of the EPA form the basis of the bio-safety regulations. These are Sections 6, 8, and 25. India's bio-safety rules apply to manufacture, import and storage of micro organisms and gene-technology products and include products made of micro organisms that are genetically engineered. The rules cover research and large-scale applications of Genetically Modified Organisms (GMOs) and products. They also deal with hazardous organisms that are not genetically modified. The rules encompass manufacture, use, import, export, storage and research. Rule 8 requires previous approval of the regulatory body for production and discharge of genetically engineered organisms or cells into the environment. Rules 10 and 11 require permission and approval to be taken for substances, products and foodstuffs and additives that contain genetically-engineered organisms or cells. The most significant provision is Rule 9, which prohibits deliberate or unintentional release of genetically-engineered organisms or cells covered under the schedule for Experimental purposes, except when approved as a special case by the regulatory body concerned. An interesting feature of the rules is its Schedule, which categorizes animal and human pathogens in terms of their risk profile.

The Bio-safety rules have been supplemented by the Biotechnology Safety Guidelines issued by the Department of Biotechnology (DBT). These Guidelines have been issued in pursuance of Rule 4(2) of the Bio-safety Rules, which require manuals of guidelines to be brought out by the Review Committee on Genetic Manipulation, a component of the bio-safety decision-making apparatus that is serviced by the DBT. The guidelines carry detailed analysis and assessment of bio-safety levels. They also provide detailed guidance on rDNA research activities, large-scale experiments, import and shipments and quality control of products

[1] A. Damodaran: Implications of Competition Policy on Biotechnology Industry in India', in P.S. Mehta ed., Towards a Functional Competition Policy for India 239, 246 (New Delhi Academic Foundation, 2005).
[2] Ibid.

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produced by rDNA technology. The guidelines were initially issued by the DBT in January 1990 under the title Recombinant DNA Safety Guidelines. In 1994 the Department issued the Revised Guidelines for Safety in Biotechnology. In 1998 further revisions were affected. The 1998 amendments were made in the light of enormous progress made since the 1990s in the fields of recombinant DNA research and its applications namely, microbial strains, cell lines and transgenic plants for commercial exploitation.

The bio-safety rules are driven by multi-layered decision-making structures. These structures carry their corresponding functions, details of which are described below:
The International Service for National Agricultural Research (ISNAR) and FAO has identified four elements that are required to be considered when developing a regulatory framework for biotechnology[3]. The first element is a legislative framework while the second element is regarding the criteria for making a product subject to regulatory assessment. The third element Concerns transparency and public involvement in decision-making while the fourth element is on approaches to risk-assessment and risk-management. India has fulfilled the first criteria by going for a mandatory legislative framework. India's bio-safety regulations clearly deal with both micro organisms and gene technology products. India has also factored in the element of economic and social impacts in assessing risks arising from GMOs and GM products. India has a decision-making system, which is well structured but needs public involvement in decision making. It is this aspect that has caused problems for India's bio-safety regulations.

Modern technology involving the use of DNA technology has emerged as powerful tool for improving both the quality and quantity of food supply and at the same time has evoked controversial debates relating to the potential impact on human health, environmental risks and also trade related issues[4].

[3] 9. Food and Agricultural Organization, Regulating GMOs in Developing and Transition Countries, Background Document to Conference 9, Electronic Forum on Biotechnology in Food and Agriculture (2003), available at http://www.fao.org/biotech/C9doc.htm.
[4] Opponents of bio-technology are skeptical about the role of bio-technology in increasing the food security; they point to the threats that it poses to sustainable development to agricultural and environmental bio-diversity and to public health, they counsel caution about the not yet well known risks of gene technology. Floma Macmillan, WTO and Environment, Sweet and Maxwell, London, 2007 quoted from 36 Nalsar Law Review
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3) THE RELATIONSHIP BETWEEN 'LAW', 'TECHNOLOGY'[5] AND 'SOCIETY'

There are two approaches for examining the interface between these concepts:

- The first approach is to evaluate how technological developments are transforming the functioning of the legal system. The most prominent aspect in this regard is the impact which information and communication technologies are having on the administration of courts, changes in procedure, approaches to research and in the functioning of lawyers' offices, law firms as well as in legal education.
- The second approach is to examine how laws try to keep pace with technological changes. With the emergence of newer technologies, uncertainties arise with regard to the application of existing laws and occasionally there is a need to create new laws to regulate their use.

The need for regulating new technologies is usually prompted by social and cultural perceptions about the advantages of a particular technology or alternatively the scope for its misuse. Such regulation could be in the form of encouragement, restrictions or even prohibition on particular technologies. On one hand, laws and policies can be structured to encourage innovation in particular fields of technology, through means such as government subsidies, tax concessions, protection of intellectual property rights and provision of funds and research facilities among others. On the other hand, the growth and use of certain technologies can be curtailed in different ways through means like safety and health regulations, criminal sanctions for misuse, higher taxation rates or even outright prohibitions. It is evident that decision-making institutions such as legislatures, courts and regulatory agencies are required to examine the constant interaction between the forces of technological change t and social attitudes[6].

4) MEANING AND DEFINITION

Bio' refers to life and 'technology' refers to the application of information for practical use, i.e. the application of living organisms to create or improve a product.

'Biotechnology means any scientific application that uses biological systems, living organisms or derivatives thereof, to produce or alter products or processes for particular use'.

The utilization of living organisms, systems or processes constitutes biotechnology'.

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[5] A definition of 'Technology' proposed by Donald Schon reads as: 'Any tool or technique, any product or process, any physical equipment or method of doing or making, by which human capability is extended'.

[6] Gregory N. Mandel, 'History Lessons for a General Theory of Law and Technology', 8 Minnesota Journals of Law, Science and Technology, 551-570 (2007).

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Based on the Collins English Dictionary definition, biotechnology is the employment of living organisms, their parts or processes, to develop active and useful products and to provide services e.g. waste treatment. The term signifies a broad range of processes, from the use of earthworms as a source of protein to the genetic modification of bacteria to offer human gene products, e.g. growth hormones.

According to the Golden Treasury of Science and Technology, biotechnology is a discipline based on the harnessing of life processes which are controlled for the bulk production of valuable substances.

Biotechnology consists of 'the controlled employment of biological agents, e.g. micro-organisms or cellular components, for favorable use'.

Biotechnology has been defined as 'Janus-faced'. This means that there are two sides to it. On one side, we know that the technology allows DNA to be modified so that genes can be moved from one organism to another. On the other, it also entails comparatively new techniques whose results are untested and should be met with care.

Biotechnology is 'the integrated use of microbiology, biochemistry and engineering sciences in production or as service operation'.

5) HISTORY OF BIO TECHNOLOGY[7]

What do stone-washed jeans and home pregnancy tests have in common with bread, cheese and wine? They are all examples of manipulating living organisms to create products or new processes. They are all products of biotechnology.

Humans have used biotechnology since the dawn of civilization. Egyptians used yeasts to bake leavened bread, the Chinese developed fermentation techniques for brewing and cheese making, and the Aztecs used Spirulina algae to make cakes. Today, when most people think of biotechnology, they probably think of recombinant DNA. Although much of modern biotechnology does deal with manipulating DNA, classical biotechnology began long before we even knew about genes or chromosomes. What began as recipes for production of food now

[7] https://www.lonestar.edu/history-of-biotechnology.htm

includes technology to enhance everything from farming to pharmaceuticals.

What we think of as modern biotechnology began around the end of the nineteenth century. By then, Mendel's work on genetics was completed and institutes for investigating fermentation along with other microbial processes had been founded by Koch, Pasteur, and Lister.

At the beginning of the twentieth century, industry and agriculture started to incorporate biotechnology. The growing automobile industry, for example, used fermentation processes to produce acetone and paint solvents. By mid-century, major advances in genetics dominated biotechnology research. The discovery that DNA carries the genetic code and the structure of the "double helix" were described by Watson and Crick. Soon, new techniques were developed to allow manipulation of DNA. Genetically engineered plants, microbes, animals, and products like insulin, highlight the future of biotechnology.

6) ORIGIN & DEVELOPMENT OF BIO TECHNOLOGY

THE most ancient biotechnological art is fermentation - in the raising of dough, the brewing of alcohol, and the production of tea, coffee, and cocoa (each of which requires a fermentation step). But the new wave of biotechnology rests on two main techniques: genetic manipulation and enzyme (or cell and cell organelle) immobilization. Genetic manipulation is used by the biotechnologist to enhance the natural genetic repertoire of a microorganism. The aim is usually to donate to the microorganism a gene for an enzyme or a hormone in such a way that the product of that gene is thenceforth synethesised by the microorganism. The successful development of genetic manipulation has rested upon the discovery of new enzymes and the improvement of old techniques by molecular biologists and microbiologists. Crucial to the success has been the development of vectors for carrying foreign genes into microorganisms. Also of great importance has been the acceleration of DNA sequencing technology. The real cornerstone of genetic manipulation, however, has been the discovery of enzymes that cut DNA at specific sites (restriction enzymes), seal the cuts up (ligase) and copy DNA from messenger RNA (reverse transcriptase). The first two of these are needed for the insertion of foreign genes into the DNA of the vector. Reverse transcriptase has become particularly important in the last two years since the revelation that the genes of higher organisms are 'split' (the coding DNA being interrupted by non-coding segments). In sharp contrast, bacteria do not have split genes and cannot decode split genes that are transferred to them. Therefore it is necessary to transfer an unsplit equivalent of the gene, which is precisely what reverse transcriptase produces from messenger RNA. Alternatively, due to recent advances in the technique of DNA synthesis, it is also possible to make purely synthetic genes at least for small peptide hormones. The use of enzymes is an older technique, applied in a number of industries from baking to detergents. But purified enzymes are soluble molecules and it is therefore not easy to separate them from the product of their labour. Furthermore it is difficult to recycle the enzyme. These difficulties have led to the development, in the late 1960s, of immobilised enzymes. The enzyme is bound chemically to a solid matrix or entrapped in a small pore gel. Immobilised enzymes have been successfully applied, for example, to the production of semi-synthetic penicillin's, to the large-scale production of fructose from maize, and to a simple assay for blood cholesterol. Immobilised cells or organelles have potential advantages when the stabilization of an enzyme is difficult, or when a coenzyme or sequence of enzymes is required for synthesis. Biotechnology may be dominated by microbial and enzyme technology, but it is certainly not synonymous with them. Both animal and plant cells have their place in the armory of the catholic biotechnologist. Successful exploitation of animal cells has been achieved, for example, by Welcome Research Laboratories in the production of interferon from virus stimulated lymphoblastiod cells. A completely distinct exploitation of animal cells lies behind the commercial production of high grade antibodies for research, diagnostic and clinical use (for example for tissue typing prior to transplantation). The key to that is the hybridomacell, an 'invention' of five years ago. Natural antibody-secreting cells neither survive long enough in culture nor produce pure enough antibodies to be a commercial source of antibody. But a hybridoma cell, the result of fusing an antibody-producing cell with a tumor cell, grows and divides continually. And all the cells from the original hybridoma secrete the same, pure antibody. Work is also going ahead in many countries on the problem of nitrogen fixation - attempting to extend the range of associations of the nodule-forming, nitrogen-fixing, bacterium Rhizobium to plants other than the Leguminosae (particularly cereals), or to transfer the nitrogen fixing genes to plants - a distant prospect, given the extreme oxygen sensitivity of the pathway. There is also the distant prospect, through genetic manipulation, of a new source of controlled genetic variability in plants to produce new high yielding or resistant varieties.

7) Biotechnology and its Various Stages of Development[8]

There are various stages in the development of biotechnology to meet the various needs of humans. Its development was basically based on observations, and applications of these

[8] Dr. Lily Srivastava, Law Relating to Science & Technology (First Edition).

observations to practical scenarios. The complexity of biotechnology is augmented due to evolution of new technologies with time, as these are based on the employment of improved technological advancements along with better understanding of various principles of life-science. If, we systemically study the developments of biotechnology up to its current stage, it can be divided into three different stages or categories: (1) Ancient Biotechnology, (2) Classical Biotechnology, and (3) Modern Biotechnology.

1) Ancient Biotechnology (Pre-1800)

Most of the developments in the ancient period i.e., before the year 1800, can be termed as ‘discoveries’ or ‘developments’. If we study all these developments, we can conclude that all these inventions were based on common observations about nature, which could be put to test for the betterment of human life at that point in time.

Food, clothes, and shelter are the most important basic needs of human beings irrespective of whether they lived in the ancient period or the modern period. The only factor that has changed is their types and origins. Food has been an inevitable need since the existence of man as well as for continuous existence of human beings. Early man used to eat raw meat, whenever they found a dead animal. However, during harsh weather, there was a paucity of food, hence, as per the saying, ‘necessity is the mother of all inventions’, which led to the domestication of food products, which is named as ‘agriculture’. In ancient times, humans explored the possibilities of making food available by growing it near their shelters, so that the basic need for food could be met easily. They brought seeds of plants (mostly grains) and sowed them near to their shelters. They understood the importance of water, light, and other requirements for the optimal growth of food plants. Similar principles and needs also led them to start domestication of different wild animals, which helped them to improve their living conditions and to satisfy their hunger. The need to hunt for animal was done away with it; as now animals were available to them at closer proximity, and also they did not have to deal with the dangerous conditions of hunting. Domestication of wild animals was the beginning of observation, implications, and applications of animal breeding. Certainly, we can say that this was the initial period of evolution of farming, which led to another needs like the development of methods for food preservation and storage. They used cold caves to preserve food for long-term storage. It also made the way for the evolution of pots to store food products, in the form of leather bags, clay jars, etc.

After domestication of food crops and wild animals, man moved on to other new observations like cheese, curd, etc. Certainly, cheese can be considered as one of the first direct products (or by-product) of biotechnology, because it was prepared by adding rennet (an enzyme found in the stomach of calves) to sour milk, which is possible only by exposing milk to microbes (although this understanding was not there, at that time). Yeast is one of the oldest microbes that have been exploited by humans for their benefit. Yeast has been widely used to make bread, vinegar production, and other fermentation products, which include production of alcoholic beverages like whiskey, wine, beer, etc. Vinegar has a significant importance because of its low pHs Vinegar is capable of preventing growth of certain microbes, and therefore, vinegar can be used successfully for food preservation. The discoveries and benefits of these observations led people to work on further improvement of the process. Fermentation was a powerful tool to improve their living conditions, even though they were ignorant about the principle behind it.

One of the oldest examples of crossbreeding for the benefit of humans is mule. Mule is an offspring of a male donkey and a female horse. People started using mules for transportation, carrying loads, and farming, when there were no tractors or trucks. Mule is comparatively easier to obtain than Hinny (offspring of a male horse and a female donkey). Mule and Hinny both have a chromosome number 63, unlike horse (64) and donkey (62).

2) Classical Biotechnology[9]

The second phase of evolution and development of biotechnology can be called 'Classical Biotechnology'. This phase existed from 1800 to almost the middle of the twentieth century. During this period various observations started pouring in, with scientific evidences. They were all very helpful toward solving the puzzle/s of biotechnology. Each and every contribution from different individuals helped to solve the puzzle and pave the path for new discoveries.

The basics for the transfer of genetic information are the core of biotechnology. This was, for the first time, deciphered in plants, i.e., *Pisum sativum*, commonly known as Pea plant. These observations were decoded by Gregor John Mendel (1822-1884), an Austrian Augustinian Monk. Mendel at that time presented "Laws of Inheritance" to the Natural Science Society in Brunn, Austria. Mendel proposed that invisible internal units of information account for

[9] Dr. Lily Srivastava, Law Relating to Science & Technology (First Edition).

observable traits, and that these 'factors' -later called as genes, which are passed from one generation to the next. However, the sad part of the story is that Mendel failed to get due recognition for his discovery for almost 34 years after his death, when other scientists like Hugo de Varies, Erich Von Tschermak, and Carl Correns validated Mendel's work in 1900. The reason why Mendel's study remained unnoticed for such a long period of time was because at the same time Charles Darwin's Theory of Evolution was so consuming that it shadowed the significance of work done by Mendel.

Almost at the same time Robert Brown had discovered nucleus in cells, while in 1868, Fredrich Miescher, a Swiss biologist reported nuclein, a compound that consisted of nucleic acid that he extracted from pus cells i.e., white blood cells (WBC). These two discoveries became the basis of modern molecular biology, for the discovery of DNA as a genetic material, and the role of DNA in transfer of genetic information. 1n 1881, Robert Koch, a German physician described the bacterial colonies growing on potato slices (First ever solid medium). Walter Hesse, one of the co-workers in Koch's laboratory, discovered agar when he asked his wife what kept the jelly solid even at high temperature of summer. She told, it is agar agar, since then nutrient agar became the most acceptable and useful medium to obtain pure microbial cultures as well as for their identification. In 1888, Heinrich Wilhelm Gottfried Von Waldeyer-Hartz, a German scientist coined the term 'Chromosome', which is considered as an organized structure of DNA and protein present in cells or a single piece of coiled DNA containing many genes, regulatory elements, and other nucleotide sequences. Other important discoveries during this period were vaccination against small pox and rabies developed by Edward Jenner a British Physician and Louis Pasteur a French Biologist.

By this time the development and growth of biological sciences seemed to be reaching to the exponential phase. The principle of genetics in inheritance was redefined by T H Morgan, who has shown inheritance and the role of chromosomes in inheritance by using fruit flies, i.e., *Drosophila melanogaster*. This landmark work of T H Morgan was named, 'The theory of the Gene' in 1926. Before the publication of Morgan's work, in 1909, the term 'Gene' had already been coined by Wilhelm Johannsen (1857-1927), who described 'gene' as carrier of heredity. Johannsen coined the terms 'genotype' and 'phenotype'. 'Genotype' was meant to describe the genetic constitution of an organism, while 'Phenotype' was meant to describe actual organism. By this time genetics started gaining its importance, which led to the start of Eugenic Movement in USA, in 1924. As a result of this, in 1924, the US Immigration Act was

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used to restrict the influx of poorly educated immigrants from Southern and Eastern Europe, on the grounds of their suspected genetic inferiority.

Almost at the same time, in Britain, Alexander Fleming a physician discovered antibiotics, when he observed that one microorganism can be used to kill another microorganism, a true representation of the 'divide and rule' policy of humans. Fleming noted that all bacteria (Staphylococci) died when a mold was growing in a Petri-dish. Later he discovered 'penicillin' the antibacterial toxin from the mold *Penicillium notatum*, which could be used against many infectious diseases. Fleming wrote, "*When I woke up just after dawn on September 28, 1928, I certainly didn't plan to revolutionize all medicine by discovering the world's first antibiotic, or bacteria killer"*. As a matter of fact vaccines and antibiotics turned out to be the best saviors of humanity. Can we attribute these two discoveries for the ever increasing population as well the ever ageing population of the world?

3) Modern Biotechnology[10]

The Second World War became a major impediment in scientific discoveries. After the end of the second world war some, very crucial discoveries were reported, which paved the path for modern biotechnology and to its current status. In 1953, JD Watson and FHC Crick for the first time cleared the mysteries around the DNA as a genetic material, by giving a structural model of DNA, popularly known as, 'Double Helix Model of DNA'. This model was able to explain various phenomena related to DNA replication, and its role in inheritance. Later, Jacob and Monad had given the concept of Operon in 1961, while Kohler and Millstein in 1975, came up with the concept of cytoplasm hybridization and produced the first ever monoclonal antibodies, which has revolutionized the diagnostics.

By this time it seemed like the world's scientific community had almost all the basic tools available to them for their applications, along with majority of basic concepts had been elucidated, which has fast forwarded the path for important scientific discoveries. Dr. Hargobind Khorana was able to synthesize the DNA in test tube, while Karl Mullis added value to Khorana's discovery by amplifying DNA in a test tube, thousand times more than the original amount of DNA. Using this technological advancement, other scientists were able to insert a foreign DNA into another host and were even able to monitor the transfer of a foreign DNA

[10] Dr. Lily Srivastava, Law Relating to Science & Technology (First Edition).

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into the next generation. The advent of HIV / AIDS as a deadly disease has helped tremendously to improve various tools employed by life-scientist for discoveries and applications in various aspects of day-to-day life. In the mean time Ian Wilmot an Irish scientist was successful to clone an adult animal, using sheep as model, and he named the cloned sheep as 'Dolly'. Craig Venter, in 2000, was able to sequence the human genome; the first publically available genome is from JD Watson and Craig Venter, himself. These discoveries have unlimited implications and applications. In 2010, Craig Venter has been successful in demonstrating that a synthetic genome could replicate autonomously. Should that be considered as a new possibility for creating life in a test tube, which could be planned and designed by human being using a pen, pencil, computer, and bioinformatics as tools? In future, can we produce life as per our imagination and whims?

Biotechnology has brought humanity to this level of comfort; the next question is, where will it take us? Biotechnology has both beneficial and destructive potentials. It is, WE who should decide how to use this technology to help humanity rather than to destroy it.

8) CASE LAWS

Understanding Basmati Biopiracy[11]

Vandana Shiva makes it clear, that yes "[w]e have won the Basmati biopiracy battle, though the war for defence of farmers' rights, indigenous knowledge and biodiversity still needs to be won". Although the battle for Basmati rice is in relative terms, over, there remains a great amount of uncertainty as to how such a blatant act of piracy could occur with minimal opposition from officials. Beyond biopiracy, Rice Tec's Basmati patent is a case of resource piracy as a natural resource (Basmati rice) was taken from a specific country without any sort of granted permission or public recognition. It is a case of economic piracy as Rice Tec used the term ''Basmati', to advertise their hybrid rice, in the hopes of appealing to customers looking for an aromatic product similar to the original Basmati. Finally, it was a case of both intellectual and cultural piracy as Rice Tec through its acquisition of Basmati, patented a key heritage piece of rice producing rural communities without permission.

The severity of Rice Tec's biopiracy cannot be underestimated, as the conglomerate was claiming to have invented the physical characteristics of Basmati such as the plant height and grain length. By claiming ownership of the rice plant itself, Rice Tec was directly threatening

[11] Dr. Lily Srivastava, Law Relating to Science & Technology (First Edition).

rural farming communities. Throughout centuries of development, Indian farmers have produced some 200,000 varieties of rice.

9) CONCLUSION

By using the techniques developed by biotechnology researchers can scientist can alter the life cycle of species by inserting a gene of wholly unrelated species and enhance disease/ stress resistance in that specie. The techniques like development of DNA vaccines and genetically altered bacteria and other transformation of life through biotechnology have been pursued for the sake of the social benefits which biotechnologist's promises. Cheaper and more effective medicines are possible when produced through biological rather than chemicals means. But appropriate balance of environmental and health concerns against economic benefits is essential for the use of biotechnological applications. People should be given awareness about both the benefits and risk of a product. They also be aware that whether the benefits justify the risks, who reaps the benefits and who bears the risk. If the risk and benefits are disproportionately distributed to different groups, the practice may be unjust which may effect the community.