Chapter 1
INTRODUCTION

Modern world is blossoming with the advent of new technologies. In the spear of technological advancement human life is touching new heights and witnessing new merits. Progress in science has taken human life to unimagined destinations. Science has added color to the human life and it has lifted the human life to novel heights. Science often and times is coming out with new innovations and technologies. The human thirst in development, human’s zeal to know new things has resulted in the innovation of novel technologies. Technology is an application of knowledge to solving specific problems or meeting identified needs. Furtherance of knowledge can be attributed to the development of technology. Development is an unending process and progress is a journey, which has infinitive destinations. The role of technology is significant in the unending process of progress and development. Technology itself is a result of progress and development towards achieving a specific goal. Since the evolution of civilization we have seen many developments witnessing the progress of the society. Different technologies played a major role in the progress of the society.

Technology is like a feather in the hat of modern world. More the number of technologies more the progress will be. Starting from the invention of motor, fermentation technology, steam engine, printing machine, telephone, radio, television, computer technology, till information technology modern society progressed a lot. In the modern day we use different technologies from dawn to desk. Modern world can be said as a hub of many technologies, which have made human life a manifested world of human thoughts. However certain developments are unimagined and unexpected and were never thought of. Biotechnology is one among such development, which was never imagined, unexpected and never had a thought of. The technological advancement in life sciences has paved its way to biotechnology known as the field of modern day miracles. The advent of biotechnology has revolutionized the progress in science. Infact biotechnology is believed not as single technology but as a culmination of different technologies. Scientific community says that it is a combination of different technologies put for use simultaneously or at a time. Technology is a result of human endeavors,
however describing and using the technology called biotechnology itself involves mental and intellectual endeavors.

DEFINITION AND MEANING OF BIOTECHNOLOGY

Basically biotechnology is a study relating to microorganisms and related things. It concerns the practical application of organisms or their components. Historically, biotechnology was an art, involved in the production of wines, beers and cheeses. Nowadays it involves a series of advanced technologies spanning biology, chemistry, biochemistry, microbiology, protein engineering, process engineering, and genetic engineering. In recent years innovations involving genetic engineering have had a major impact on biotechnology. In 1919 Karl Erkay a Hungarian engineer coined the term biotechnology. At that time the term biotechnology encompassed the production of products from raw materials with the aid of living organisms. The term biotechnology is a combination of two words ‘bio’ and ‘technology’. The word bio is taken from Greek word ‘bios’, which means life. Technology means application of scientific knowledge for practical purposes to get desired results. Biotechnology means the scientific knowledge that uses life or living entities like microorganisms, plants, and animals for practical and commercial purposes to get desired results.

Biotechnology is defined in numerous ways in different terms, however there is no universally accepted definition. Biotechnology is very dynamic and progressing rapidly therefore it is not possible to define biotechnology in exact terms. There are many definitions of biotechnology and yet there is more confusion as to what it is and what is involved in the practical activity. Many organization and working parties have published reports where an attempt has been made to define biotechnology. The United Nations

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1 Howard, B. Rock man, Intellectual property law for engineers and scientists, Wiley-interscience, New Jersey, 2004, Pg. No. 259
2 See: Sreenivsulu N.S, and Dr. C.Basvaraju, “Biotechnology and patent law”, THE WORLD JOURNAL OF INTELLECTUAL PROPERTY RIGHTS, Serials publications, New Delhi, Volume: 1, Number 1-2, Jun-Dec 2005
3 See generally, Sreenivsulu N.S, “Biotechnology inventions and patent protection”, INTELLECTUAL PROPERTY RIGHTS, edited by Dr. C. Basavaraju, Serials publications, New Delhi, First edition, 2006
5 M.M. Ranga, Animal biotechnology, Agro bios India, Jodhpur, 1999-2000, Pg. No.2
6 See: Sreenivasulu N.S, “Information technology and biotechnology”, Dr. Talwar Sabanna (edited), GLOBALISATION AND WTO, Serials publications, New Delhi, 2006
congress’s office of technology assessment\(^7\) defines biotechnology to mean “any technique that uses living organisms to make or modify a product to improve plants or animals or to develop microorganisms for specific uses.”\(^8\) The European Federation of Biotechnology (EFB) considers biotechnology as the integration of natural sciences and organisms, cells, parts thereof, and molecular analogues for products and services.\(^9\) British biotechnologists define biotechnology as an “application of biological organisms system or processes to manufacturing and service industries”. Japanese biotechnologists define biotechnology to mean a technology using biological phenomena for copying and manufacturing various kinds of useful substances.\(^10\)

However biotechnology is broadly defined as any technique that uses living organisms or parts of organisms to make or modify products to improve plants or animals or to develop microorganisms for specific uses. It is not a single technique rather a combination of different techniques utilized to manipulate living organisms in directed fashions. Perhaps biotechnology is multidisciplinary\(^11\) in nature, a series of advanced technologies spanning biology, chemistry, biochemistry, microbiology, protein engineering, process engineering and genetic engineering put together and collectively called as biotechnology”.\(^12\) In simple sense biotechnology means the application of technology or scientific knowledge to the biological processes\(^13\). It involves human intervention to the natural biological processes by way of technical contribution to arrive at desired results.\(^14\) Therefore biotechnology is an application of human invented techniques to natural biological processes. The inventions of biotechnology are called as biotechnological inventions. Biotechnological invention is defined to mean,” any

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\(^7\) See: United States Office of Technology Assessment reports, 1981 and 1984  
\(^8\) M.Ranga, Animal biotechnology, AGROBIOS (INDIA) Jodhpur, 1999-2000, PG. No. 2  
\(^10\) Supra Note. No. 7  
\(^11\) M.Ranga, Animal biotechnology, AGROBIOS (INDIA) Jodhpur, 1999-2000, PG. No.3  
\(^12\) Sreenivasulu N.S and Dr. C. Basavaraju, “Biotechnology and patent law”, THE JOURNAL OF WORLD INTELLECTUAL PROPERTY RIGHTS, serials publications, New Delhi, Volume.1, Number 1-2, June-Dec 2005  
\(^14\) See: Sreenivasulu N.S, “Information technology and biotechnology”, Dr. Talwar Sabanna (edited), GLOBALISATION AND WTO, Serials publications, New Delhi, 2006
invention which concern a product consisting of or containing biological material or process by means of which biological material is produced, processed or used.”  

HISTORICAL DEVELOPMENT AND THE EMERGENCE OF BIOTECHNOLOGY

The story of the use of biological systems for the fulfillment of human needs perhaps started in 6000 B.C. Infact biotechnology can be traced back to approximately 6000 B.C when Sumerians and Baby lonians first used yeast to make beer. Egyptians were baking leavened bred by 4000 B.C and in China fermentation processes were discovered for preserving milk by lactic acid bacteria to make yogurt and to produce cheeses. Beginning with fermentation use of biological processes experienced many changes over centuries. The modern biotechnology can be traced back to the eighteenth century when smallpox was practiced to invoke an immune response and prevent development of more serious cases later on in life. During eighteenth century cross-fertilization was discovered and crop rotation was practiced to increase yield. The process of sterilization was also discovered during the eighteenth century.

In the nineteenth century Louis Pasteur called as the father of biotechnology demonstrated fermentative ability of microorganisms. During that time epidemiological observations were used to develop the hypothesis of cross-infection by spread of childbed fever from mother to mother by physicians, which led to the hypothesis that physicians wash their hands after examining each patent. Another milestone during the nineteenth century was the invention of a process of beer fermentation by Louis Pasteur in 1873. He proved that microbes were responsible for fermentation. He also invented the pasteurization process, which involves heating wine sufficiently to inactivate microbes. In the nineteen forties complicated techniques were introduced to the mass cultivation of microorganisms to exclude contaminated microorganisms. Infact Gregor Mendel’s

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15 See: Chapter VI, Rule 23B(2) of the European Patent Convention EPC.
16 M.Ranga, Animal biotechnology, AGROBIOS (INDIA) Jodhpur, 1999-2000, Pg. No.1
18 Ibid
19 M.Ranga, Animal biotechnology, AGROBIOS (INDIA) Jodhpur, 1999-2000, Pg. No.1
21 Ibid
presentation of the law of heredity development of Pastures rabbis vaccine, discovery of antibiotics, in 1929 and their large scale production in nineteen forties, the isolation of DNA by Crick and Watts in 1953, the discovery of chromosomes, discovery of the protozoan plasmodium as a cause of malaria, the investigation of anthrax were all milestones in the development of biotechnology.\textsuperscript{22}

But greatest revolution took place in nineteen seventies and nineteen eighties when product of interaction between the science of biology and technology came into wider existence and the relationship got the name biotechnology.\textsuperscript{23} Modern biotechnology has got its roots in the early nineteen eighties when recombinant DNA technology or genetic engineering developed.\textsuperscript{24} Modern biotechnology is mostly concerned with and concentrated on genetic engineering. Commercial production of human insulin through recombinant DNA technology in the United States showcased the potential of recombinant DNA technology.\textsuperscript{25} The development of process engineering and protein engineering that involves methods of protein production through recombinant DNA technology adds another feather to the wings of modern biotechnology.\textsuperscript{26} The development of biotechnology can be classified into three generations.

First generation of biotechnology

The first generation of biotechnology is based on empirical practice and minimal scientific or technical inputs. These techniques dates back to the Stone Age and involves using of biological organisms such as bacteria, yeasts, enzymes and traditional methods of fermentation to produce food and drink such as bred and wine. Production of cheese and beer by using microorganisms was the milestone in this generation.

Second generation of Biotechnology

\textsuperscript{23} M.Ranga, Animal biotechnology, AGROBIOS (INDIA) Jodhpur, 1999-2000, PG. No.1
\textsuperscript{24} See generally, Howard. B. Rock man, Intellectual property law for engineers and scientists, Wiley-interscience, New Jersey, 2004, Pg. No.259
\textsuperscript{25} Research on recombinant human insulin was begun in the early 1980's and resulted in commercial production of human insulin by the incorporation the gene coding for human insulin into bacteria. Since bacteria replicates rapidly insertion of gene into bacteria and its expression could yield high production of insulin. See: Ibid. Pg. No. 260
\textsuperscript{26} Recombinant protein development involves isolation purification and in vitro production of intended protein. It requires the incorporation of a particular gene coding for particular protein in an intended host body (say bacteria) and expressing it.
This generation begun during the interwar period when developments in fermentation technology using pure cell culture and sterile manufacturing facilities begun to yield new products. During this generation innovations such as acetane, butanol, glycerol, vitamin B2, citric acid, and lactic acid took place. The invention of penicillin in 1928 was the milestone in the second generation.

**Third generation of biotechnology**

Three important technologies namely, tissue cell culture, Hybridoma technology and recombinant DNA technology also known also known as genetic engineering were developed in the third generation. These three technologies represent the modern biotechnology. Tissue culture technology is used to establish cell lines, which are used for medical diagnosis and treatments. Hybridoma technology is used in the production of human monoclonal antibodies, which are used to supplement natural human antibodies in medical treatments.

The invention of DNA by Crick and Watson in 1953 was the turning point in the third generation of biotechnology. The recombinant DNA technology is the technique that involves manipulation of genetic materials of a living being to get desired results. Indeed it is recombinant DNA technology, which brought biotechnology into limelight. Modern biotechnology is defined on the basis of genetic engineering and is mostly concerned with genetic engineering. The inventions of biotechnology are playing a vital role in the industrial sector. Almost there is no field where biotechnology has got no impact. Most of the biotechnology inventions fall in the sphere of food, agriculture and medical industry. Certain inventions of biotechnology fall in the sphere of forestry, environment, energy and chemistry.

**APPLICATION AND SCOPE OF BIOTECHNOLOGY**

Biotechnology is an interdisciplinary pursuit and it is multidisciplinary in its application. The term multidisciplinary describes a quantitative extension of approaches to problems that commonly occur within a given area. In the recent past a characteristic feature of the development of science and technology has been the increasing resort to

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multidisciplinary strategies for the solution of various problems. One such idea of multidisciplinary pursuit has resulted in the crystallization of a new discipline called biotechnology. Being multidisciplinary biotechnology involves the marshalling of concepts and methodologies from a number of separate disciplines and applying them to a specific problem in another area. Besides biotechnology has got diverse application in different fields. The successful application of biotechnology depends upon the working co-operation of the experts in different fields. The scope and application of biotechnology is increasing day by day. At one point of time biotechnology was limited to fermentation of beer, to day it is significant in revolutionizing certain areas of industry like; agriculture, animal husbandry, medical and pharmaceutical industry, forestry, fisheries, environment protection, chemical industries, food, beverages and many. In order to understand the scope and significance of biotechnology it would be proper to discuss its application in different fields.

**Agriculture and biotechnology**

Agriculture is a sector, which feeds the hungry of the world. The proceeds of the sector are used at least twice or trice in a day by everyone. For many economies including India agriculture sector is the backbone. The demand for high production in the sector is increasing day by day, as there is increase in the population. In order to meet the hunger demands of the increasing population there should be increased production. Further directly or indirectly the industrial sector is depending on the agriculture sector for raw material. Therefore demand for increased production in the sector is very much felt. In ancient times agriculturalists were practicing different methods to increase production. Changing crop in order to avoid continuous cropping of same crop, crossing, budding, grafting and tissue culture were methods practiced to increase the production.

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29 Infact biotechnology seems to be a resort to the different problems existing in the society like poverty, diseases, pollution, drought and like many.


32 The raw material for industries comes from the agriculture sector. For example sugar industry uses sugar cane as raw material to produce sugar. Production of certain medicines depends on the agriculture products. Further chemical industry uses certain substances of plants in the production.
However the application of biotechnology in the agricultural sector is giving rise to revolutionary changes in the field promising to yield good results.\textsuperscript{33} To day in the era of biotechnology traditional methods such as crossing, budding and tissue culture for increasing production are replaced by methods such as genetic engineering, showing prominence in yielding the best results.\textsuperscript{34}

There are plants that grow withstanding water shortages. There are few plants, which resist pests and weeds.\textsuperscript{35} Further there are plants, which give high yield. How it would be if plants in drought areas could grow with minimum use of water?\textsuperscript{36} How it would be if regular crops could show resistance to pests and weeds? How it would be if regular crops could give high yield? It is no more just an imagination but it is seemingly possible through biotechnology.\textsuperscript{37} Biotechnology through genetic engineering, a willow in its armory is promising to produce such super crops with desired qualities. Any crop or plant could be engineered for desired results. By manipulating the genome of plants genes coding for certain features like resistance to pests, weeds, herbicides,\textsuperscript{38} tolerance to drought conditions, high yield could be isolated and incorporated into an intended crop.\textsuperscript{39} This technique of isolating and incorporating genes is called genetic engineering.\textsuperscript{40} It

\textsuperscript{35} Ibid, Pg. No. 168
\textsuperscript{36} Sreenivasulu N.S and Dr. C. Basavaraju, “Biotechnology and patent law”, THE JOURNAL OF WORLD INTELLECTUAL PROPERTY RIGHTS, serials publications, New Delhi, Volume.1, Number 1-2, June-Dec 2005
\textsuperscript{37} See generally Sreenivasulu N.S, Information technology and biotechnology, GLOBALISATION AND WTO, Dr. Talwar Sabanna, (edited) Serials publications, New Delhi, First edition, 2006
\textsuperscript{39} Genetic engineering could also be used to incorporate the features of two or more plants into one plant. For example if one plant is pest resistant another is high yielding. Genes coding for pest resistance and high yielding could be isolated from both plants and could be incorporated into an intended plant which in turn possess both qualities high yield and resistance to pests. However incorporation of more than one foreign gene into a plant may not express both the genes. In fact researches are going on on incorporation of more than one foreign gene into an intended plant.
\textsuperscript{40} Genetic engineering originally developed in bacteria; the technique was first used to move novel genes into plants in 1983. (See Hooykas and Schilperoot 1985, for review) Since than progress in crops has been dramatic. As early as in 1986 field trials or crops engineered for insect resistance were under way in the United States. See Garville J. Parsley, Agricultural Biotechnology: opportunities for international development, C.A.B International, Wallingford. U.K, 1990, Pg. No. 108
involves marshalling of genes to manifest characteristic features of plants in order to get better and improved crops bestowed with desired characteristics.\textsuperscript{41}

This technique of marshalling genes gave birth to genetically engineered plants with qualities such as high yield, capacity to resist pests, insects and weeds and also capacity to withstand drought conditions.\textsuperscript{42} If an engineered plant gives high yield than the regular plant at the same cost of production it will definitely benefit the farmer and as well as the society. Further a plant that is resistant to insects, weeds, pests and herbicides will reduce the cost of production.\textsuperscript{43} As per the estimations 20 to 40 percent of the worlds agriculture production is lost due to pests, weeds and diseases and additional 40 percent would suffer the same fate without pesticide application.\textsuperscript{44} The global estimate of loss due to plant diseases in 1987 was approximately US $ 90 billion.\textsuperscript{45} Therefore biotechnology capable of producing crops that are featured to resist viruses, pests and weeds plays a vital role in the modern day agriculture.

In the developed countries impact and application of biotechnology in the agriculture sector is highly felt. In the United States of America 15 transgenic plants were given market permission in the year 1995. Further 13 plants were waiting for permission.\textsuperscript{46} In Europe reportedly 496 transgenic plants were released during 1986-1994.\textsuperscript{47} Slowly but gradually, the developing world is catching up with the developed world. In India some field trials of transgenic plants were conducted during 1995-96.\textsuperscript{48} Few multi national companies active in the agriculture sector have established tie-ups

\begin{thebibliography}{99}
\bibitem{41} Manu Luv Sahalia, Intellectual property rights: many sides to a coin, Universal Law Publishing Co. Pvt. Ltd, Delhi, 2003 edition. Pg. No.130 and 131, See also
\bibitem{42} Sreenivasulu N.S and Dr. C. Basavaraju, “Biotechnology and patent law”, THE JOURNAL OF WORLD INTELLECTUAL PROPERTY RIGHTS, serials publications, New Delhi, Volume.1, Number 1-2, June-Dec 2005
\bibitem{46} Shivaramaiah Shantaram, Jane F. Montgomery, Biotechnology, Biosafety and Biodiversity-scientific and ethical issues for sustainable development, Oxford and IBH publishing Co. Pvt. Ltd, New Delhi, 1999, Reprinted 2000, Pg. No. 19
\bibitem{47} Gene Exchange, December, 1994, Pg. No. 7
\bibitem{48} See: The annual report of the department of biotechnology, Government of India, 1995-96
\end{thebibliography}
with Indian companies like Proagro seed company, Mahyco Seed Company. Infact Mahyco Seed Company is conducting trials of imported BT cotton in India. Recently Novavax an American Biotech Company tied up with Bharath Biotech Company based in Hyderabad. Many multinational companies are showing interest to have tie-ups with Indian companies are intending to open their branches in India. It is a healthy sign for the development of biotechnology in India. Application of biotechnology has increased production levels and decreased the cost of production. Biotechnology produced engineered crops like BT cotton, BT rice, BT soybeans, BT wheat, BT tomato and BT potato. Compared to regular crops, genetically engineered wheat, rice are said to yield up to 30 percent more under same cultivation conditions. It is evident that genetically engineered plants are capable of giving better quality, higher yield and resisting pests and weeds. Therefore the application of biotechnology in the sector is yielding fruitful results.

**Animal husbandry and biotechnology**

In the field of animal husbandry application of biotechnology intends to produce high yield of milk, flesh and woolen. Biotechnology is being applied in the animal husbandry through tissue culture or genetic engineering. Tissue culture involves isolating and culturing of cells or organ of an animal in vitro (outside the body) for a desired result. Tissue culture in animals is useful in testing drugs and medicines. Genetic engineering of animal involves isolation of specific genes coding for certain characteristics and incorporation and expression of the same in an intended animal to get desired results.

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49. See: Sreenivasulu N.S, and Dr. C. Basvaraju, “Biotechnology and patent law”, THE WORLD JOURNAL OF INTELLECTUAL PROPERTY RIGHTS, Serials publications, New Delhi, Volume:1, Number 1-2, Jun-Dec 2005
50. See: Vaccines for an influenza pandemic, The Hindu daily, dated March 18, 2006, Pg. No. 11
53. See: GM rice-top of the crops, The Hindu daily, August 24, 2005 Pg. No. 11
54. M.M. Ranga, Animal biotechnology, Agro bios India, Jodhpur, 1999-2000, Pg. No. 6
55. Ibid, Major techniques of animal biotechnology Pg. No. 6
different animals with different genetic setup. Crossing a disease-resisting animal with a high milk-yielding animal may result in offspring’s possessing both the desired qualities of disease resisting and high milk yielding. Now genetic engineering is promising even more potential to get desired results in animal husbandry.56

We have seen few animals which resist diseases but not capable of giving high yield of milk or flesh or woolen. We have seen animals that give high yield of milk or flesh or woolen but incapable of resisting diseases. How it would be if the same animal possesses both the features of resisting diseases and giving high yield. Genetic engineering a wing of biotechnology promises to materialize such a dream in animal husbandry. Genetic engineering made it possible to isolate the genes coding for specific characteristics from different animals and to incorporate the same into an intended animal. For example gene coding for high yield can be isolated and incorporated in to an animal capable of resisting diseases or vice versa, the result being the animal possessing both the characteristics.57 Through this technique genetically engineered sheep capable of giving high yield of flesh and woolen, genetically engineered cow capable of giving high yield of milk were produced.58 Further cow’s milk can be enriched with high protein values by incorporating a particular gene coding for such specific protein into its body. On the same lines flesh of sheep can also be enriched with high protein values. On the same lines through marshalling of genes there produced genetically engineered monkey, rabbit, and mouse.59

Besides genetically engineered animals are used in testing drugs, medicines and therapies. It is a regular practice in the medical field to test drugs or medicines or therapies on animals before letting the same for human use. Some times genetically engineered animals are produced solely for the purpose of testing drugs and medicines. Oncomouse is one such example where it is produced with a sole objective of testing cancer disease. Further certain proteins, antibodies and enzymes produced inside body of different animals are having medicinal values. Such proteins if produced commercially

56 See: The annual report of the department of biotechnology, Government of India, 1995-96
57 Such isolation and incorporation should take place at the stage of 4 to 8 cell stage from inception of the animal through egg and sperm fertilization.
58 See generally Sreenivasulu N.S, Information technology and biotechnology. GLOBALISATION AND WTO, Dr. Talwar Sabanna, (edited) Serials publications, New Delhi, First edition, 2006
can be used for preparing drugs and medicines. Perhaps the body of pig is known as pharmaceutical factory.\textsuperscript{60} It produces many protein and antibodies inside its body, which have got significant medicinal values. Biotechnology promises commercial production of such proteins through isolation and incorporation of the specific gene coding for such protein into an intended organism. Such genetically engineered organism produces the desired protein in its body. Bacteria are rapid in multiplying and producing proteins in a short period of time. Therefore generally bacteria are used to produce proteins of different organisms (animal, plant and human being) by incorporating the respective gene. Hepatitis-B virus vaccine is developed in the above manner from genetically engineered yeast.\textsuperscript{61}

Further genetically engineered animals are used as bioreactors to produce human metabolic products. For instance Tracy is a sheep whose germ line contains a genetic construction comprising a human gene resulting in the production of human protein in its milk.\textsuperscript{62} On the same line any human gene expressing a specific protein could be incorporated into animals like cow or sheep in order to get milk or flesh enriched with intended human protein. Very recently an American company announced that it has produced vegetarian pigs. They might have incorporated genes from plants into pig, making it to possess qualities of such plants. Meanwhile in the recent past animal husbandry witnessed drastic changes due to the application of biotechnology. Perhaps the application of biotechnology in the field resulted in animals possessing qualities like high yield of milk, flesh or woolen at comparatively low cost of production. Further it gave rise to the production of human metabolic products in animal bodies. Besides biotechnologically invented genetically engineered animals are being used for testing medicines, drugs and vaccines.

**Medical and Pharmaceuticals and biotechnology**

\textsuperscript{59} See: M.M. Ranga, Animal biotechnology, Agro bios India, Jodhpur, 1999-2000, Pg. No.6
\textsuperscript{60} See: Sreenivasulu N.S, and Dr. C.Basvaraju, “Biotechnology and patent law”, THE WORLD JOURNAL OF INTELLECTUAL PROPERTY RIGHTS, Serials publications, New Delhi, Volume: 1, Number 1-2, Jun-Dec 2005
\textsuperscript{61} M.M. Ranga, Animal biotechnology, Agro bios India, Jodhpur, 1999-2000, Pg. No.6. The vaccine has become available in 1986
\textsuperscript{62} See: Sreenivasulu N.S, and Dr. C.Basvaraju, “Biotechnology and patent law”, THE WORLD JOURNAL OF INTELLECTUAL PROPERTY RIGHTS, Serials publications, New Delhi, Volume: 1, Number 1-2, Jun-Dec 2005
Medical and pharmaceutical industry caters the health needs of the society. The industry keeps an eye on the advancements in science and technology in order to produce new drugs and medicines. Time and often medical and pharmaceutical industry is coming out with new drugs and medicines to provide cures for different diseases. Meanwhile Biotechnology is trying its hand in catering the health needs of the society through its application in the medical and pharmaceutical sector intending to produce new and innovative drugs, medicines, therapies and surgical methods in an innovative way. The application of biotechnology in the field has resulted in finding cures and medicines for many diseases. Biotechnology represents a powerful alternative to traditional methods of drug discovery that involves laborious screening of thousands of organic compounds found naturally in soil plants and molds. The advent of recombinant DNA technology or genetic engineering has paved way to the invention of innovative medicines and drugs possessing natural antibodies and proteins.

Living beings body naturally produces certain proteins, enzymes and antibodies to fight against diseases and attacks of virus. Genes inside the body gets activated to resists and to fight against diseases or virus attacks by expressing certain protein or antibody or enzyme. Through biotechnology it is possible to isolate specific genes coding for such antibodies and proteins in order to produce the same commercially on large scale. Isolated genes could be incorporated into any microorganism say bacteria to produce the protein or antibody that the gene is coding for. The resulted protein or enzyme or antibody could be made use of in producing medicines and cures to diseases. For example human body produces natural insulin. Diabetic patients suffer from inadequate production of insulin in their bodies therefore they need to supply insulin to their body. Human insulin can be commercially produced through genetic engineering by isolating the gene coding for insulin in the human body and incorporating the same into a bacteria.

63 See generally Sreenivasulu N.S, Information technology and biotechnology, GLOBALISATION AND WTO, Dr. Talwar Sabanna, (edited) Serials publications, New Delhi, First edition, 2006
64 Supra Note. No. 63
66 Disease is a result of attack of foreign body like virus or bacteria on our body. Our body reacts to such attack by producing certain antibodies or proteins. The genes coding for such proteins or antibodies gets activated and expresses at the instance of attack
Such commercial production of human insulin comes for a great help for diabetic patients. Likewise body of women produces a hormone called relaxin. The gene coding for the hormones gets activated and expresses the hormone to relax the body of a women suffered pain during while delivering a baby. Through genetic engineering the same hormone could be commercially produced and used in producing painkillers. 67

In 1982 genetically engineered insulin got market approval in U.K and U.S.A. In the same way in the mid nineteen eighties genetically engineered growth hormone got approval. Further genetically engineered proteins to treat heart attacks and strokes, new vaccines for foot and mouth disease, monoclonal antibodies to boost body’s defense system against cancer and other diseases were introduced.68 Hepatitis-B a major public health problem was threatening the entire world. In 1986 a vaccine derived from genetically engineered yeast was made available for Hepatitis-B.69

Further animal body produces certain antibiotics and proteins, which resists diseases. Such proteins and antibodies could be commercially produced through the isolation of respective gene and incorporation of the same in an intended organism. For examples pig’s body is known as a factory of pharmaceuticals as it produces different antibodies and proteins having medical values inside the body. Such antibodies and proteins can be commercially produced to be used in the production of medicines and drugs. Like wise proteins and antibiotics produced in the body of any living being could be commercially produced to use in the production of medicines and drugs.70 Till the time more than 4000 antibiotics have been isolated from different living being and at least 50 have achieved wide usage.71 Between 1982- 1992 nine pharmaceuticals produced through biotechnology were approved for marketing. Insulin for treating diabetics, growth hormone for treating growth deficiency, Hepatitis-B vaccine for Hepatitis-B prevention, interferon to treat cancer and viral infectors, Anti-T-cell to treat organ

68 Ibid
69 M.M. Ranga, Animal biotechnology, Agro bios India, Jodhpur, 1999-2000, Pg. No.4-10
70 Living beings body is a composition of cells. Inside every cell there lies a genome that contains chromosomes. Chromosomes are the combination of DNAs. The expressive region on the DNA is called as gene. Gene expresses certain proteins or antibiotics, enzymes or hormones.
transplantation, tissue plasminogen activator to treat cardiovascular disease, erythropoietin to treat anemia, interleukin-2 to treat cancer\textsuperscript{72} were introduced.

Besides biotechnology has introduced innovative surgical methods, diagnostic techniques where genetically engineered microorganisms are being used. Further new therapies have been invented to treat hereditary or genetic diseases, which once thought as not curable.\textsuperscript{73} Gene therapy a biotechnological method of curing diseases, cures genetic or hereditary diseases and stops the disease from passing on to the next generation. Now it is possible to cure hereditary diseases by the removal or suppression of specific gene causing the disease.\textsuperscript{74}The first gene therapy was patented in the United States in 1995. To date the United States patent office has issued dozens of gene therapy patents.\textsuperscript{75}Further monoclonal antibodies produced through biotechnology are used in cancer diagnosis therapy and diagnosis of sexually transmitted diseases.\textsuperscript{76} Besides stem cell research a new wing of biotechnology intends to find cures for many diseases. Stem cell research is also intends to produce tissues for use in organ transplantation. Further another biotechnological method embryonic research highly controversial is promising to find cures and medicines to different diseases. Therefore it can be inferred that medical industry is poised to radical changes with the application of biotechnology.

Comparatively the cost of production of biotechnologically invented drugs and medicines is low than that of cost of traditional methods of production of drugs and medicines. As per the estimation roughly US $ 175 to 300 million is required to develop a new biotech medicine. However the development of a medicine through regular methods requires US $ 300 to 500 million.\textsuperscript{77} To date biotechnology has brought more

\textsuperscript{72} Ibid, Pg. No. 134
\textsuperscript{74} By incorporating a foreign gene the effect of the gene causing hereditary could be nullified and suppressed or by the removal of the gene the disease could be stopped from passing on to the next generation.
\textsuperscript{75} Jasmine Chambers, Patent eligibility of Biotechnological inventions in the U.S Europe and Japan: How much patent policy is public policy? George Washington International Law review, 2002
\textsuperscript{77} See: Danial Vassella, Novarties role in 21\textsuperscript{st} century drug development, 15 Nature biotechnology 485 (1997)
than 50 new medicines to the market and more than 350 medicines and therapies at various stages of clinical testing and garnered in excess of $16 billion in sales in 1998.\textsuperscript{78}

Biotechnology has revolutionized the medical and pharmaceutical industry with its innovative way of medicine production.\textsuperscript{79} The combination of biotechnological and traditional method of producing medicines is yielding outstanding results.\textsuperscript{80} It invented cures and therapies for many diseases. Researches are going on to find vaccine against typhoid, cholera, AIDS and cancer. Recently Novavax an American Biotech Company tied up with Bharath Biotech Company based in Hyderabad for producing vaccines for different diseases including the recent outburst of “bird flu”.\textsuperscript{81} The role of biotechnology in antibody body production, vaccine production and in disease control is indispensable. The diseases, which were once thought of as not curable, have been cured through therapies invented by biotechnology. It may not be untrue if biotechnology is called as modern day miracle in the light of its application and outstanding results in the field of medical and pharmaceuticals.

\textbf{Environment protection and biotechnology}

To day protection of environment is one among the priorities. Abatement of pollution is a matter of concern all over the world. Various efforts are being made to preserve and protect the environment from being polluted.\textsuperscript{82} Pollution can have catastrophic and immediate effect on birds, animals and also on the balance of ecology. It is identified that oil-derived compounds, toxic chemicals, industrial waste, sewage, domestic waste, gas and releases of vehicles mainly cause environment pollution. Biotechnology has got its role to play in the abatement of pollution and in the protection of environment. Infact natural microorganisms play a vital role in the protection and preservation of environment. In the treatment of waste, sewage, pollutants and other

\textsuperscript{78} Pharmaceuticals manufacturers association annual report for 1998; SCOTORRISON & GLEN GIOVANETTI BRIDGING THE GAP, 13\textsuperscript{th} annual biotech industry report Einst and Young, 1999

\textsuperscript{79} Novarties and Ciba Gigzy two major biotechnology firms have engaged themselves in the promotion of the application of biotechnology in the medical and pharmaceutical field.


\textsuperscript{81} See: Vaccines for an influenza pandemic, The Hindu daily, dated March18, 2006, Pg. No. 11

\textsuperscript{82} See: Sreenivasulu N.S, and Dr. C.Basvaraju, “Biotechnology and patent law”, THE WORLD JOURNAL OF INTELLECTUAL PROPERTY RIGHTS, Serials publications, New Delhi, Volume: 1, Number 1-2, Jun-Dec 2005
contaminated material microorganisms contribution is significant. Treatment of waste and sewage also helps in preventing the spread of infectious diseases.83

Meanwhile the marriage between biotechnology and environment gave rise to a discipline called environmental biotechnology that studies the application of biological systems and processes in waste and pollution treatment and management.84 Different biotechnology processes that involve biological catalysts and microorganism to degrade, detoxify have been developed for water, gas, soil solid waste, domestic waste, industrial waste treatment and contaminating chemicals.85 All biotechnology processes make use of the metabolic activities of microorganisms in treating waste.86

For the first time Dr Chakraburty87 showed the way to use modern biotechnology in the abatement of pollution and the protection of environment. His invention a genetically engineered microorganism capable of eating oil spills showed the world how microorganisms can be used in the pollution control. It is accepted that microorganisms naturally do play a role in the abatement of pollution by degrading wastes and sewages. However genetically engineered microorganisms proved to be very effective in treating different pollutants. Deep shaft fermentation system a biotechnology invention is used in the treatment of wastewater. The deep shaft system involves creating a hole in the ground divided to allow the cycling and mixing of wastewater air and microorganisms.88

Further composting is also a biotechnological process that grows microorganisms to decompose solid organic wastes into a stable, sanitary like material considerably reduced in bulk, which can be safely returned to the environment. Like wise biotechnology invented different processes to treat wastes and to abate pollution. Besides the application of biotechnology resulted in modifying the existing pollution treatment processes yielding better results. Biotechnology seems to be promising clean and green environment through its innovative methods of pollution control and waste treatment.

85 Ibid, Pg. No.153
86 Ibid: Pg. No. 142-143
87 See: Diamond V. Chakraburty (1980) USSC 447
Therefore the application of biotechnology in the protection of environment is becoming inevitable as pollution is growing day by day and the need for the protection of environment is also growing day by day.

**Food, beverages and biotechnology**

Biotechnology seems to feed the hunger needs of the society by guaranteeing right to food. Biotechnologists say that only way to provide food security is to genetically engineer crops. Biotechnology has introduced Genetically Modified Food (GMO) to the world, which has revolutionized the food industry. Genetically modified food proved to have high protein levels and vitamins compared to regular food. Genetically modified food promises improved quality, nutrition, safety and long preservation. Application of biotechnology in the food industry has got influence on the taste, color, consistency, quality, preservation, health and cost of food. Consumable food plants like rice, wheat, tomato, potato and the like are genetically engineered to increase the consumable value. A Chinese study demonstrated that 10% increase in yield was witnessed with insect-resistant genetically modified rice. Genetically modified rice and wheat gives high yield compared to regular rice and wheat. Further genetically modified tomato or potato possesses longer shelf lines and gives high yield compared to regular tomato or potato.

Besides in the production of beverages, cheeses, sauce, mushrooms and other fermented foods biotechnology plays a significant role. As early as in 6000 BC itself beer was produced through fermentation technology; one among different technology in

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89 M.M. Ranga, Animal biotechnology, Agro bios India, Jodhpur, 1999-2000, Pg. No.3
93 See generally, Genetically Modified Foods: Food for thought in the Economist, 19 June 1999, Pg. No. 23-7
94 The Hindu daily, August 24, 2005, Pg. No. 11
Further biotechnology is playing vital role in the production of soft drinks and alcoholic beverages. Substances such as sugary materials fruit, juices, honey or starchy materials (grains or root) are used with varied levels and fermented with microorganisms to produce alcohol, beer or soft drinks. Using leaves and pulp biotechnology produces non-alcoholic beverages such as coffee, tea and cocoa. Further production of fermented milk, butter and cheeses is taken help from biotechnology. Biotechnologically derived lactic acid is significant in preservation of vegetable for a long time. Likewise the application of biotechnology yielded many good results. Therefore it can be inferred that biotechnology is playing a significant role in guaranteeing right to food to the society.

Other applications of biotechnology

Biotechnology has influenced many fields in different ways. Biotechnology plays a vital role in the mining industry in extracting metals. In the chemical industry biotechnology is being used to develop or split chemicals. In the forestry biotechnology techniques such as tissue culture, genetic engineering and cloning are used to conserve and preserve extinction species. In the field of aquaculture biotechnology is used to increase fish production. Fish cultivation could be improved through gene transfer and cloning. In the same manner of transforming genes from one animal or plant to another animal or plant genes could be transferred to fishes to get better results like high protein values, to install disease resistance, to express any nutritional or medicinal proteins and also high yield.

Application of biotechnology is not confined to certain fields, day by day the scope, significance and application of biotechnology is rapidly growing. It may not be untrue in saying that today there is no field where biotechnology has got no application. Modern day could not be expected without the impact of biotechnology. The WIPO study

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96 Howard B. Rock man, Intellectual property law for engineers and scientists, IEEE press, WILEY INTERSCINCE, A JOHN WILEY & SONS, INC., PUBLICATION, New Jersey, 2004
98 Ibid. Pg. No.157
99 Ibid. Pg. No. 169
100 M.M. Ranga, Animal biotechnology, Agro bios India, Jodhpur, 1999-2000, Pg. No.8
on the importance of Biotechnology for National Growth and Development stresses \(^{101}\) on the significance of biotechnology in the modern world. \(^{102}\) Biotechnology has changed the entire scenario of the world with its innovations involving human ingenuity and labor. The collaboration of human ingenuity with natural biological processes has yielded great results. The addition of human ingenuity and intellectual labor in an innovative way gave rise to many new products and processes. Different innovations of biotechnology having diverse application in different fields could be classified as follows.

**Biotechnological processes**

1) Process to invent any new genetically engineered microorganisms, plants or animals.
2) Process to genetically engineer microorganisms, plants or animals.
3) Process of isolating and incorporating genes, DNA gene fragments and cells from a living being and incorporating into any other living being.
4) Process of deriving proteins through expressing a foreign gene in a host organism.
5) Process or method of treating genetic or hereditary diseases. (Gene therapy)
6) Process of fermentation of beverages, cheeses.
7) Process to clean up pollutants in the environments.

**Biotechnology products**

1) Genetically engineered microorganism, plant or animal.
2) Isolated and purified cells, genes, DNA or gene fragments from the body of any living being.
3) Proteins identified in the body of living beings and commercially produced outside the body.
4) Genetically engineered food and beverages.

However wherever one goes, whatever one may do law will be watching everyone at every point of time. Whatever progress human has made, whatever unpredicted milestones human has reached, whichever innovative technologies science has come out with, human being is never far away from the regulating clutches of the law. Law is a

\(^{101}\) See: WIPO study on the protection of Inventions in the field of Biotechnology, EIPO/Cornell University, 1987.
controlling mechanism; it is a regulating framework and is the watchdog of the society. Any thing without proper regulations may result in liessaz-fair. The fruits of scientific innovations cannot be gained and enjoyed without the proper regulations. There shall be some legal mechanism to regulate any scientific sphere in order to reap the fruits of desire. There should be some mechanism to recognize and protect the intellectual property rights in the scientific innovations. As a regulatory mechanism law is expected to regulate and protect the intellectual property rights in these innovations and developments of science and technology.

Intellectual property rights are the results of human ingenuity and intellectual labor. Ingenuity and intellectual labor in biotechnology inventions must be identified and encouraged through rewards. Patents reward ingenuity and intellect in producing any invention. Patent is a reward for the efforts of ingenuity and labor of intellect in inventing a new product or process. The recent study of WIPO on the industrial property protection of biotechnology inventions aims to promote biotechnology inventions. The study intends to protect the biotechnology inventions in the light of their enormous potential to cater different needs of the society. Patent law offers protection to new inventions of products and processes. Inventions of biotechnology capable of yielding better results in different fields deserve patent protection. Biotechnology invented products and processes must be given patent protection under the patent laws.

Perhaps many a times law is not keeping pace with the developments of science and technology. The result is the lack of proper legal mechanism to regulate and protect the novel innovations of science and technology. Patent is a method of offering protection to inventions. An invention can be patented on the satisfaction of certain requirements under the patent law. However the traditional patent law does not recognize living beings as inventions. Living organisms were not considered as patentable under the traditional patent laws. Since biotechnology gives rise to living inventions it is not possible to give

patent protection to biotechnology inventions under the traditional or old patent laws. Therefore there is a need to recognize biotechnology inventions as inventions by modifying the existing patent laws in order to offer patent protection.

The developed countries like U.S. have witnessed the biotechnology developments earlier to the developing countries like India. Comparatively countries like U.S. have made necessary alterations or amendments to the existing laws to provide patent protection to the biotechnology inventions. Indeed U.S judiciary has liberally interpreted the existing patent law of U.S to provide patent protection to biotechnology inventions. It can be said that the evolution of biotech law in the present world was much influenced by the liberal approach of the U.S judiciary. In the absence of proper legal mechanism the law Courts have come out with liberal interpretation of existing patent laws to recognize and protect the biotechnology inventions. One such example is Dr. Chakraburthy’s case, wherein U.S court has accorded patent protection to a biotechnology invention made by Dr. Chakraburthy. Besides the legal environment in U.S. is such that “anything under the sun can be patentable provided that there is some human intervention. But the situation is different in the countries like India. In India living things like plant, animal, and other living organisms are treated as common heritage. Since patent gives rise to private property rights no one can obtain patent and privatize common heritage. Further monopolizing and privatizing the living beings through patents is considered as immoral and unethical in India.

In the United States the common heritage principle has got little significance unlike India. Developed countries are liberally interpreting the patent laws to provide patent protection to biotechnology inventions. International conventions like European Patent Convention (EPC) and the Trade Related aspects of Intellectual Property Rights (TRIPS) postulate for intellectual property protection for all type of inventions including biotechnology inventions. Further the Budapest treaty provides for the deposit of newly invented microorganisms for the purpose of providing patent protection. Besides the European directive on the legal protection of biotechnological inventions intends to offer patent protection to different biotechnology inventions. These conventions say that member states must come with proper legal mechanisms to protect biotech inventions.
Lot of groundwork was done before offering patent protection to biotechnology inventions.

Since biotechnology concerns life or living beings, it gives rise to certain interesting questions. The patentability of biotechnology inventions (living beings) and ethics involved in patenting such inventions is repeatedly questioned. Practical problems in patenting, granting, maintaining and enforcing biotechnology inventions remained unresolved since the birth of biotechnology. At this juncture the present research work tries to evaluate the law relating to biotechnology inventions. The thesis makes an attempt to examine the legal framework providing for patenting of biotechnology inventions. There identified certain research problem and the solving of which is the aim of the research work. On the basis of the identified problems there drawn certain hypothesis, which may be the probable reach of the work. The thesis objects to solve the identified problems by setting forth specific objectives on the basis of the hypothesis drawn.

**RESEARCH PROBLEMS**

1. Law is not keeping pace with the technological developments. Biotechnology and its inventions are a prone to stretch the frontiers of the present legal system.

2. The existing legal system and the patent laws are not effective enough to protect and regulate the biotechnology inventions.

3. The present patent law is stretching its frontiers to give patent living inventions like; microorganisms, plant (lower life forms) animal and human genetic material (higher life forms).

4. There are inherent complexities involved in granting and maintenance of biotech patents. It requires special attention while granting biotech patent keeping in mind the different complexities involved in.

5. There felt difficulties in introducing ethics into the patent law. The present legal system is forced to extend its cover in an unprecedented way compromising with ethical and moral standards of the society.
OBJECTIVES

1. An evaluation of biotechnology and identification of the legal framework to regulate biotechnology. The basic thirst of the study is to evaluate the law relating to patenting of life.

2. A probe into the patenting of living beings invented through biotechnology and identification and the evaluation of the legal mechanism to regulate the patenting of animals and human genetic materials.

3. An examination of the granting procedure and maintenance of biotechnology patents.

4. A probe into the enforcement of biotechnology patents and available remedies for infringement of biotech patents.

5. An investigation into the Compulsory licensing of biotech patents in the public interest.

6. An ethical inquiry into the patenting of life and ethical evaluation of different biotechnology inventions. An investigation into the human genetic research and ethical and legal complexities involved there in.

HYPOTHESIS

1. In the absence of legal mechanism to regulate biotechnology, the biotechnology inventions capable of catering the different needs of the society have not been accorded with proper recognition and the patent protection.

2. Due to the fact that law is not keeping pace with the technological developments, it is not yet possible to properly regulate the patenting of life comprising of patenting of microorganisms, plants, animal and human genetic materials.

3. Due to the lack of proper measures in order to give special attention to the patent grants to the biotech patents the present procedure of granting and maintenance of biotech patent is adhoc and troublesome.

4. Despite the existing legal mechanism the irregular release of engineered organisms and dangers of biotech inventions like invention of biological invention and use will endanger the environment and biodiversity.
5. Due to the enormous development-taking place in the field of biotechnology the values underlined in the ethical and moral standards of the society are being deteriorated.

IMPORTANCE OF THE STUDY

In the modern world Intellectual property rights are playing a vital role. Scientific and technological innovations have been accorded patent protection to encourage innovative and creative spirit. Protection of innovations through patents aims for the better use and utilization of inventions in the broad interest of the society. At this juncture the present study is important as it evaluates the scientific sphere called biotechnology. The present research work throws light on the evolution of biotech patent law; hence it is useful in knowing the voyage of patent law towards offering patent protection to biotechnology inventions. Further the research work investigates into the patentability of biotech inventions/living inventions; hence it is helpful in knowing the requirements that a biotech invention should satisfy in order to get a patent.

The study examines the granting maintenance procedures of patents on life; hence it is useful in knowing the procedural formalities involved in granting and maintenance of biotech patents. Further it also probes into the enforcement of biotech patents; hence it is advantageous in enforcing biotech patents against infringements and also in getting suitable remedies. Besides the research work is useful to the compulsory license seekers as it highlights the law relating to the compulsory licensing of biotech patents. The study is a useful source to the lawyers, law scholars and law students as it identifies and evaluates the law relating to the biotechnology. It is also important to the lawmakers and policy implementers as it evaluates the existing legal system on the regulation and enforcement of biotechnology.

PLAN OF THE STUDY

Given the case the enormous growth of biotechnology the thesis intends to focus on the evolution of biotech patent law offering protection to biotechnology products and processes. It aims to probe into the developments in patenting living beings invented through biotechnology such as microorganism, plants animals and human genetic
material. The thesis objects to trace the evolution of biotech patent law to Europe and America. Given the inherent complexities and technical nature of biotechnology inventions the thesis plans to investigate into the patentability requirements that a biotechnology invention must satisfy. It intends to conduct an enquiry into the additional requirements that a biotechnology invention must satisfy along with regular requirements of patentability. Further it tries to throw light on the liberal interpretation of the patentability requirements in the case of biotechnology inventions.

Further the thesis tries to examine the granting procedure of biotechnology patents. It objects to highlight the examination of a biotech patent application and it’s possessing before the patent office. It aims to highlight the process of maintenance of biotech patents for a fixed term. Besides the thesis intends to look into the enforcement of biotechnology patents and adjudication of infringements. Compulsory licensing of biotechnology patents is also dealt with in the thesis. In the light of objections to the patenting of biotechnology inventions the thesis intends to conduct an ethical inquiry into the ethics in patenting of biotechnology inventions. It tries to investigate into the social, ethical and moral standards of the society in the light of patenting of living beings. In view of the exhaustive discussion of various issues involved in the biotechnology and patenting of life, the thesis tries to identify the possible risks associated with biotechnology inventions. The thesis intends to conclude with certain recommendation and suggestions on the findings made for the better regulation and management of biotechnology inventions.

**METHODOLOGY ADOPTED**

For this study on biotechnology and law: patenting of life doctrinal, analytical and critical methods have been adopted. Relevant patent legislations, International conventions, have been referred, analyzed and critically evaluated. Various International and National documents, journals, publications and literature has been referred. The present approach of the law in the United States of America, Europe and India with reference to biotechnology and its inventions has been analyzed, and evaluated.
SOURCES OF THE RESEARCH

Primary sources:

For this research work National legislations of U.S.A, Indian and European Union on patent law, intellectual property rights and human rights have been refereed. International conventions on patent law, intellectual property rights and human rights have been refereed.

Secondary sources:

Further National and International literature on the subject, journals, publications, periodicals, reports of different committees from different Nations on the subject, National and International documents, articles, publications, reports of surveys, opinion poles, debates and the Internet is taken assistance from.

CHAPTERISATION

Chapter: 1 Introduction

The chapter introduces the subject biotechnology with its theoretical, philosophical foundations. The history of biotechnology and its voyage since the invention of fermentation technology till the present Recombinant DNA technology or Genetic engineering, Gene therapy, Assisted reproduction technology, Stem cell research is discussed. Different types of biotech inventions such as biotech processes, biotech products microorganisms, transgenic plants, transgenic animals, and human genetic materials such as genes, DNA, fragments of genes and DNA, proteins, enzymes, polypeptides, and hormones are highlighted. Further the application and scope of biotechnological inventions in enormous in the present world and the significance of the biotech inventions in the fields of agriculture, food, animal, fisheries, forestry, environment, medical and pharmaceutical fields is also discussed. Besides the chapter sets out the research problems identified for the study. It highlights the hypothesis framed and objects set forth for the research work. The importance and plan of the study and methodology adopted for conducting research is also being discussed in the chapter. Besides the sources of material for the research and chapterisation of the thesis is also given a mention.
Chapter: 2 Evolution of Biotechnology patent law

This chapter deals with the voyage of patent law in the evolution of biotech patent law. The doctrine of product of nature which was an obstacle in the evolution of biotech law the developments in overriding the doctrine in opening avenues to the biotech patent law is discussed. The developments in patenting lower life forms such as microorganisms and plants are discussed. Further developments in patenting higher life such as animals and human genetic material are also discussed. The evolution of biotech patent law has its roots in Europe and America. Besides the instances and developments in this regard are highlighted. Landmarks in the evolution of biotech patent law like: Chakraburty decision in the United States the TRIPS agreement and European Unions Directive on the legal protection of Biotechnological inventions are highlighted in this chapter. The chapter discusses the evolution of biotech patent law in different phases. Starting from patenting of microorganisms, patenting of plants, patenting of genes, patenting of human genetic materials is discussed. Starting from the first patent of living invention on fermentation of beer till the prohibition of human cloning is elaborately discussed. The evolution of biotech patent law in the United States, Europe and India is discussed separately.

Chapter: 3 Patentability of biotechnology inventions

This chapter discusses the patentability of biotech inventions. The criteria on the basis of which biotech patents are granted are highlighted. The requirements under the patent law that a biotech invention must satisfy before the grant of a patent are highlighted. Special requirements that a living invention or biotech invention must satisfy in order to get patent are also highlighted. The complexities involved in patenting of life forms such as microorganisms, plants, animal and human genetic material are discussed. The difference between a discovery and invention that is very important in proving the novelty of living inventions is discussed with adequate examples. The patentability of biotech inventions in the United States, Europe and India is discussed separately.

Chapter: 4 Grants, maintenance of biotechnology patents.

The chapter contemplates the complete picture of the granting procedure of a biotechnology patent at both national and international level. The chapter contemplates how international biotechnology application could be filed under the Patent Co-operation
The chapter sets out the procedure of filing, processing, examining and publishing of a biotechnology patent application by the patent office. Further the chapter brings out the mode of searching prior art with reference to the invention claimed in the applications. The effect of a grant of a national patent as well as international patent grant is being discussed. Besides the chapter throws light on the rights that a biotechnology patent grant confers on the patentee. Besides the procedure to maintain a biotechnology patent during the term of a patent is also dealt with. The process for surrendering and revocation of a biotechnology patent in the public interest is also discussed.

Chapter: 5 Enforcement and compulsory licensing of biotechnology patents

This chapter discusses about the infringement of a biotechnology patents. The chapter investigates into the enforcement mechanism of biotechnology patents. It details on the procedure involved in the encroachment of biotechnology patents. It gives information about the persons who can file suit against biotechnology patent infringement. Further possible remedies available against the infringement of biotechnology patents are discussed with the help of relevant case laws decided in the legal systems of U.S.A, the European Union and India. In addition it throws light on the possible defenses available to the alleged infringer. Besides the chapter details on the compulsory licensing of a biotechnology patent.

Chapter: 6 Ethics in patenting biotechnology inventions

Life is a creation of God who is the creator and owner of it. No individual could manipulate and hold life. Manipulation of life amounts to playing god. Patenting of life amounts to commodification of life as a market commodity against the intrinsic values of life. Patenting of life amounts to slavery, violation of dignity and human rights. The idea of manipulation of living beings and owing through patenting is unethical. In this background the present chapter evaluates the patenting of different life forms including human genetic material. The chapter throws light on how the patenting of life forms got through the ethical objections. The voyage of life patenting in crossing the ethical hurdles in a way exploding and altering the moral standards of the society is being discussed. How the potential benefits and capacity of the biotech inventions have sidelined ethical considerations has been discussed. Further the capacity of the biotechnology in producing miracles such as removing or incorporating genetic materials, cloning tissues of a living
being and cloning of a living being to produce an exact copy is discussed and evaluated from the angle of ethics and as well as from the angle of the welfare of the society. Besides the chapter details why and how the biotech industry is restricted from not cloning human being or from producing transgenic human.

**Chapter: 7 conclusion and suggestions**

This chapter concludes the thesis by highlighting the potential benefits of biotechnology. The potential dangers of biotechnology are also being discussed in the chapter. The findings of the research work on the basis of the problems identified are enumerated. Further the chapter gives an overview of biotechnology, the evolution of law relating to biotechnology. It provides a glimpse of patentability of biotechnology inventions and the procedure for the granting of patent on such invention. An overview of enforcement of biotechnology inventions and ethics involved in it is also discussed. Besides the chapter highlights the suggestions and recommendation made on the study.