Chapter 7

Conclusion and suggestions

Ingenuity should receive liberal encouragement. Ingenuity should be identified, recognized through rewards. The potential benefits that ingenuity may result in should not be undermined. Biotechnology inventions are the result of application of human ingenuity to the biological processes. This technology having diverse application in different fields produced non-natural living beings and such other inventions associated with life capable of catering different needs of the society. It is not possible to list out the fields where biotechnology is being applied; it is only possible to give an illustrative list of its application. The application of this technology yielded great results enhancing the capacity of the fields where it is being applied. In the field of agriculture the application of biotechnology resulted in crops with qualities like; high yield, pest resistance, insect resistance, herbicide resistance and also capacity to withstand water shortages. Crops with above qualities reduced cost of production at the same time increasing the yield. In the field of animal husbandry biotechnology produced animals with qualities like high yield of milk, woolen, flesh and also quick growth.

In the field of medicine and pharmaceuticals biotechnology produced miracles. It produced cures and medicines for many diseases. Biotechnology made it possible to isolate and commercially produce natural proteins, enzymes and antibodies produced inside the body of living beings. These proteins and antibodies are used in the production of medicines, vaccines and drugs to cure different diseases. Biotechnology is able to produce medicines for hereditary diseases, which were once thought as not curable. Hereditary diseases are being cured through a biotechnological process called gene therapy. Researches are going on in the field of biotechnology with an ambition to find vaccine for cancer and AIDS. Further production of drugs through biotechnological process is cheaper compared to traditional method of drug production.

In the field of environment protection and pollution control the role of biotechnology is vital. Biotechnologically processes are being employed and biotechnologically produced microorganisms are being used to combat pollution in the environment. Further biotechnology has revolutionized the food and beverages industry
with its innovative genetically modified food. Genetically modified food is promised to have high nutritional values. At the same time genetically modified food can be preserved for a long time. Consumable foods such as tomato, potato if genetically modified possesses high nutritional values. There are many fields where biotechnology is being applied to get desired results. The inventions of biotechnology having diverse applications and having enormous potential to cater the needs of the society deserve to be protected.

The inventions of biotechnology, which evolved in an unpredicted and unprecedented manner, have come through a long struggle for recognition and reward. The voyage of struggle was not so smooth as there witnessed many negative and positive strides. Patent is a reward for human ingenuity in the form of monopoly rights. Biotechnology inventions a result of human ingenuity to the biological processes too deserves patent protection. The law relating to patenting of biotechnology inventions could be traced to the Supreme Court of America. In the year 1980 in Chakraburty case the Supreme Court of America had laid foundation to the evolution of biotech patent law. Indeed the Chakraburty decision had a great impact on the traditional patent laws, which were against patenting living beings. The decision opened doors for the patenting of living beings opening a new era in the history of patent law. The decision was to patent living beings such as microorganisms. This decision was traced back to in patenting plants, animals and human genetic materials in the latter days.

Though the evolution of biotech patent law or patent law on biotechnology inventions could be traced back to the above decision in America, there witnessed certain encouragement to the patenting of biotechnology inventions even earlier. In 1893 itself Louis Pasteur got a patent on a fermentation process of beer using yeast. During nineteen sixties in Germany patents were claimed on living beings. Infact the Supreme Court of Germany had upheld patents on living beings. However these instances could not attract public interest unlike the Chakraburty decision. The patent office of America as well as the Supreme Court interpreted the patent law in an innovative and liberal way to patent living beings. Following the suit other countries through out the world started granting patents on living beings. In particular the European Union was quick enough to adopt the philosophy of America in allowing patents on living beings. The patent law on biotech is
judge made law. It was the judiciary, which took initiative to patent living beings, which was followed by the legislature at latter stages. The voyage that began with patenting microorganisms witnessed patenting of plants there after animals and also human genetic materials. The coming into being of the TRIPS agreement has uniformed the patent law on biotechnology inventions throughout the world. Now all the member countries of the TRIPS agreement including U.S, Europe and India do provide for patenting of different living beings like transgenic microorganisms, plant animal and human genetic material produced out of biotechnology. However there is a uniform opinion throughout the world that transgenic human beings are not patentable. Further cloned human embryo is not patentable and its commercial use is prohibited. On the same lines processes to alter germ line genetic identity of human beings is also not patentable.

At every instance of claiming living beings patent office and the judiciary have considered the invention in the light of its enormous potential to fulfill different needs of the society. The fulfillment of requirements of patentability by the biotechnology inventions was a matter of concern. The traditional requirements of patentability such as novelty, non-obviousness (inventive step), utility (industrial application) and written description are also applicable to biotechnology inventions. An invention that constitutes a patentable subject matter can be patented on the satisfaction of the above requirements. Till the Chakraburty decision living beings and biotechnology inventions did not constitute patentable subject matter, as living beings were not considered as not patentable. The Supreme Court of America brought living beings produced through non-natural processes like biotechnological process within the purview of patentable subject matter with its decision in Chakraburty. Therefore now biotechnology inventions are patentable on the satisfaction of the requirements of patentability.

Inventions, which are new, are patentable, a subject matter that was in existence in the nature, which is not considered as new, is not patentable on its discovery. Biotechnology inventions are not completely new. The raw material for the biotechnology inventions is living beings existing in the nature. These living beings are altered or modified to possess certain characteristics, which they were not earlier. The modification of living beings in possessing new characteristics in a non-natural way renders a living being new. Further the requirement of inventive step was of paramount
importance in patenting living beings. The inventive step could be located in making the living being to possess certain desired features. The modification and incorporation of desired qualities into a living being is considered to constitute inventive step.

Further the utility of biotechnology inventions is presumed and undisputed. Infact the utility of biotechnology inventions was never doubted. The use and industrial application or commercial potent of the biotechnology inventions is profound. The potential of biotechnology inventions in serving the needs of the society as a whole is undisputed. In addition to the above requirements an invention must be described in a clear and complete manner to enable a person skilled in the art to practice the invention. The best mode of practicing the invention shall be described in the application. However, it is accepted fact that it may not be possible to describe a living being complete and clear manner. Since biotechnology inventions are living beings the fulfillment of the requirement of written description is doubtful. Therefore in order to compensate the non-fulfillment of the written description requirement the deposit of the invention is preferred.

The requirements of patentability are co-related in case of biotechnology inventions. An invention which is not a patentable subject matter cannot be patented through it satisfies all the other requirements of patentability. The fulfillment of inventive step co relates it self with the fulfillment of the requirement of novelty. The fact that existing living beings are modified through biotechnology is related to both the requirement of novelty and industrial application. Modification of existing living beings renders the living beings novel, the incorporation of novel features into a living being through modification constitutes inventive step. Further inventive step is also related with the requirement of written description. An invention is said to be made when it is actually conceived. The conception of the invention involves conception of the physical and chemical properties of the invention. When the physical and chemical properties structure and sequence is identified then it can be said that an invention is made. The description of the invention involves description of its physical and chemical properties along with its structure and sequence. In order to describe the invention one ought to know its chemical and physical properties. Therefore what is not conceived that cannot be described. The conception of the invention not only satisfies the requirement of inventive step but also helps in describing the invention.
On the fulfillment of the requirements of patentability patents are granted. Patents on biotechnology inventions are granted on an application. The application shall be made in prescribed form along with prescribed fee. The application shall accompany the description of the inventions with or without drawings. Further the deposit of the invention with complete details of the depositing authority where the invention is deposited shall accompany the application. Inventors can claim international protection to their inventions by filing international patent applications. Patent office examines the application to check its compliance with the requirements. The patent office assesses the credentials of the invention in the light of the knowledge existing in the public domain. A search for existing prior art will be conducted to find any invention, publication, or patent already in existence on claimed invention. In case of existence of prior art on the invention in the form of publication or pending patent application or patented invention the application will be rejected. Assistance of experts is being taken in assessing and examining the application in the light of inherent complexities involved in the biotechnology inventions. Further in conducting search also expert’s assistance is taken by the patent office. Patents are granted for a term of twenty years on the successful fulfillment of requirements and completion of procedures. Different states follow different methods in granting patents. The U.S follows post grant opposition where in patent is granted first and the same afterwards will be advertised to invite oppositions if any. Patent could be revoked on successful opposition.

The grant of patent confers on the applicant/owner certain exclusive rights over the invention such as right to use, make, sell, or exploit the invention. Further by informing the patent office the patent owner can assign or license the patent. However except the owner nobody can exploit the invention. If anybody without the authorization uses or exploits the invention it does constitute infringement of the patent. Patents are enforced against infringement. The patent owner can file a suit against infringement claiming injunction to stop the infringer from continuing with his activities constituting infringement of his patent or damages or accounts of profits to compensate the loss suffered by him. In infringement suits defendants generally claim non-fulfillment of requirements of patentability such as lack of inventive step, inadequate written description, failure to disclose the best mode of practicing the invention or failure to
deposit the invention etc as defenses. On successful defense by the defendants on the above grounds or on successful proof of invalidity a patent could be revoked.

Since biotechnology inventions have diverse application in different fields licensing or compulsory licensing of a biotechnology patent is a common phenomena. Compulsory licensing is an instrument in the hands of the government to keep the invention available to the public. In case of patent owners failure to exploit the invention or at the instance of improper exploitation or when the invention is not available to the public at affordable prices any interested person can seek compulsory license. However countries like U.S are against compulsory licensing of biotechnology inventions. The TRIPS agreement states that in the public interest compulsory license can be granted. This provision of the TRIPS is not mandatory therefore there is no compulsion on the member states to provide for compulsory licensing of biotechnology inventions.

Meanwhile the ethical and moral standards of the society objects modification and patenting of living beings. Almost all the religious groups are against patenting of living beings, but the same is not been considered in the light of the enormous potential of living beings fetching benefits to the society. Living beings are considered as the creation of God and patenting of the same is considered unethical and immoral. The approach is that human being cannot create living beings and cannot own living beings through patent. Morally speaking a living being’s life cannot be monopolized and living beings cannot be treated as market commodities through patents. Patenting living beings amounts to slavery, which is against the dignity of living beings. Ethicists say that human being cannot take the life of other living being for granted in modifying and owing the same. Further they say that a small alteration in an existing living being does not render it totally new; hence it does not qualify for patenting.

Meanwhile the developments in the field of biotechnology and its enormous utility are prone to under mine the ethical considerations. The approach is that ethics could be sacrificed in the light of benefits of biotechnology inventions. The present trend is that we cannot stick to the age-old ethical and moral standards in the light of innovative developments of biotechnology promising to cater the needs of the society. Here the stand seems to be to overweigh the ethical considerations with the potential of biotechnology. But there shall be some balancing approach where ethics and the benefits
of biotechnology may be balanced. At one point of time patenting of any living being was considered as unethical. At present transgenic microorganisms, plants, animals and human genetic material are patented outweighing the ethical concerns. It can be said that in the light of the potential benefits of the biotechnologically produced living beings ethics have been sacrificed.

However all invention of biotechnology are not allowed to be patented as it is not possible to totally undermine or give up the ethical standards of the society. Biotechnology is capable of producing transgenic human beings but the same cannot be allowed by sacrificing the ethical and moral standards. Producing a transgenic human being and its patenting is considered as highly immoral and unethical. On the same lines exploitation of human embryos and patenting the same is considered unethical. At the same time it is considered unethical to alter the germ line genetic identity of human beings. Modifying or sacrificing the ethical considerations should stop at allowing patents on human genetic material. It should not further to produce and patent transgenic human being, which would be a gross violation of social order and ethics. Ethics and morality should be used to balance and check the development of the biotechnology. In case of transgenic human beings and human embryos ethics outweighs potential benefits. But in the case of transgenic microorganism, plant, animal and human genetic material benefits of the invention outweigh ethics. Though protection is assured to biotechnology inventions through patents there is a need to evaluate its merits and demerits. As patenting of biotechnology inventions is too complex and rising serious questions it would be pertinent to analyze its potential benefits and merits on the basis of which patents are being granted undermining ethics. The merits or advantages of biotechnology can be summarized as follows.

**Advantages of biotechnology**

1. Biotechnology is capable of producing high yielding, pest resisting, and herbicide resisting crops.
2. Application of biotechnology in animal husbandry resulted in animals with qualities such as high yield of milk, woolen and flesh
3. Biotechnology produced innovative medicines, drugs, vaccines, cures and surgical methods. It is possible to cure even hereditary diseases through biotechnological processes.

4. Biotechnologically produced animals could be used for testing new medicines, drugs, and vaccines prior to the use of the same for human beings.

5. In the field of food and beverages the application of biotechnology resulted in consumable foods with high nutritional values.

6. For the people who are in need of organs biotechnology extends great help. Organs produced through biotechnology could be transformed to the needy.

7. In the field of environment biotechnology is promising to be helpful in combating pollution and in maintaining ecological balance.

8. Infertile couples can have children through biotechnology-assisted reproduction.

9. Through cloning extincting animals plants and other species could be conserved and preserved in order to maintain biological diversity.

The other side of the coin:

The potential of biotechnology is undoubted but the other face of biotechnology is destructive in nature. The potential benefits of biotechnology are many but at the same time there could be some problems due to the misapplication or misuse of biotechnology. Misuse of biotechnology may give rise to inventing destructive biological weapons. Biological agents such as bacteria and virus may be misused for the purpose of producing biological weapons for the mass destruction. Microorganisms with destructive qualities like; heightened infection efficacy may cause danger to the living beings. Using of such microorganisms for mass destruction, as biological weapons will have destructive impact. Release of such microorganism with infected diseases may cause danger to the health and environment. Further biotechnology may be misused to produce artificially created plants and animals to disturb and destroy ecological balance in any particular locality. Even the irregular release of transgenic organisms may disturb the safety and balance of the environment. In such circumstances there may be a threat to the bio-safety. Further gross misuse of biotechnology may result in producing transgenic human being, which is a gross violation of public order and morality. Society has accepted transgenic microorganisms, plants and animals. But the same society is not ready to accept
transgenic human being. The demerits and dangers of biotechnology could be summarized as follows.

**Disadvantages of biotechnology**

1. One important disadvantage of biotechnology is that it causes sufferings to animals in manipulating them.
2. The results of many of the biotechnology methods and processes are having no guarantee but doubtful as the success rate of biotechnological methods like; cloning is only fifteen percent.
3. The application of biotechnology may result in too much control of living beings and biological processes giving rise to health hazardous to plant animal and human being and also environmental risks.
4. Suppressed or removed genes through biotechnology may result in mutation and extinction of genes disturbing ecological balance. Further transformed genes may jump into other species-giving rise to unforeseen problems.
5. The irregular release of genetically modified organisms into the environment may result in unforeseen and irreparable consequences.
6. Biotechnology may be misused in producing biological weapons by using microorganisms like bacteria, viruses with destructive genes, which may release harmonious gases when expressed.
7. The ethics and morality of biotechnology inventions is frequently questioned and vehemently opposed.

After a thorough study of biotechnology and law particularly focusing on patenting of life there could be drawn few inferences. The evaluation of the law relating to the patenting of biotechnology inventions and the investigation into the patentability of biotechnology inventions has resulted in few findings. Further an inquiry into the granting and maintenance of biotechnology patents and the examination of the enforcement of biotechnology patents resulted in certain findings. On the same lines the probe into the ethics involved in patenting biotechnology inventions resulted in specific findings. On the whole the findings of the research work can be summarized as follows.
Findings of the research:

1. The evolution of patent law on biotechnology inventions is not smooth but confusing. There is a need to streamline the same with necessary adjustments in the existing law.
2. The judiciary, which was active in the evolution of biotech patent law, gave liberal and sometime unforeseen interpretation of the law.
3. The regular requirements under the existing patent law have been relaxed to extend patent protection to the biotechnology inventions.
4. The patent granting procedure especially in India is cumbersome. In U.S.A it takes one and half year to grant a patent in Europe it takes three years to grant a patent. But in India it takes more than five years to grant a patent.
5. The patent office may not be having expertise and therefore it is finding difficulty in evaluating and assessing patent applications claiming biotechnology inventions.
6. The enforcement mechanism of biotechnology patents is finding difficulty in disposing biotechnology patent infringement suits given the complexity and technical nature of the biotechnology inventions.
7. The provision for granting compulsory licenses of biotechnology patents is not uniform in the states and the TRIPS agreement provisions are not mandatory on the member states in granting compulsory licenses.
8. There is an urgent need to rationalize and uniform the biosafety laws in the light of patenting of biotechnology inventions throughout the world.
9. There is a possibility of misusing the potential of biotechnology in producing destructive biological weapons against social order.
10. There is a possibility of producing a transgenic human being by abusing biotechnology in violation of public order and morality. There expected doubts that given the potential of the biotechnology there might have produced transgenic human being already.

There is always lies scope for improvement and there will be always a margin for developments. Like wise the law relating to biotechnology and patenting of life could be strengthened and streamlined by adopting certain modifications. On the basis of the
above findings of the research work the following suggestions can be made which if adopted brings the existing law in tune with the latest developments in the field of biotechnology. The suggestions may be adopted for the proper regulation and management of biotechnology inventions.

**Suggestions and recommendations**

1. The fluctuating approach of the judiciary may be put a break to by removing ambiguity in the municipal laws with reference to the patenting of biotechnology inventions.

2. As patenting of different biotechnology inventions is universally accepted except transgenic human beings, it may be proper if the municipal laws are modified and stream lined by providing for specific exclusions and prohibitions in the light of the ethical and moral standards of the society to exclude transgenic human being.

3. There may be adopted a Universal declaration or convention on the prohibition of transgenic human being and cloning of human being for reproductive purpose as a whole.

4. The time period for the patent grants in India shall be reduced. The procedure shall be amended to grant patent within in three years given the dynamic nature of biotechnology where changes are taking place in a rapid pace. Further in case of pending of the patent application for more than three years before the patent office due to the reason of delay in the office or due to the pending of opposition proceedings or due to the pending of appeal proceedings the domestic laws may be amended to adjust the patent period accordingly.

5. Given the complexities involved in the field of biotechnology and difficulty in processing and patenting of biotechnology inventions there shall be an expert committee in the patent offices to assist and advice in assessing and evaluating the patent applications claiming biotechnology inventions.

6. In the light of technical nature of biotechnology inventions the enforcement mechanism may take assistance from expert committees in adjudicating and enforcing biotechnology inventions.

7. The TRIPS agreement can be amended to mandate compulsory licensing of biotechnology inventions on the satisfaction of certain conditions. The word
‘may’ in the provision providing for compulsory licensing can be replaced with the word ‘shall’ to mandate the granting of compulsory licenses of inventions in member states on the satisfaction of necessary conditions.

8. In the light of patent protection to biotechnology inventions and in view of the release of genetically engineered organisms into the environment there shall be some universally applicable biosafety mechanism addressing the dangers posed by the inventions of biotechnology to ensure safe production, storage, transfer, release, use, and exploitation. For this purpose necessary amendments can be made to the CBD specifically addressing safety in biotechnology.

9. Given the potential of biotechnology in producing biological weapons there can be an amendment to the Convention of Biological Diversity (CBD) to prohibit misuse of biotechnology and production of biological weapons in order to guarantee ecological balance and biological diversity.

10. The United Nations (UN) may take initiative to strictly implement the Convention on the prohibition of the development, production and stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destructions by promoting ratification of the convention among states to ensure safety from bacteriological or biological or toxin weapons. Further if there produced any such weapons already, the UN should initiate for the mass destruction of such weapons.