CHAPTER-V
CONCLUSION AND SUGGESTIONS

The history of mankind is replete with different revolutions. The progress of society is influenced by different technologies. Ranging from industrial revolution and electronic revolution till the information technology revolution, mankind has aptly tackled these revolutions. In fact, society at large has been very much influenced by this technological revolution called biotechnology. This technology is a culmination of human invention and natural processes. No doubt biotechnology is not new but exists since ancient times. In those days fermentation technology was used to produce and preserve goods for a long time. With addition of genetic engineering or recombinant technology the same fermentation technology is now called biotechnology. In fact, it is genetic engineering which is capable of manipulating living organisms and of making such organisms to perform and function in a way different from the natural ones. Because of genetic engineering, biotechnology is called the technology of modern-day miracles. Perhaps, biotechnology proved itself to be in the field of miracles when it produced genetically modified or non-natural living organisms.

Ever since a genetically engineered micro-organism was granted patent in 1980 in the US, the field of biotechnology gained enormous significance. Patent on genetically engineered micro-organism was followed by patent on genetically engineered plant, animal, and engineered human genetic material. Today, biotechnology is capable of producing even a genetically engineered human being. When patent was granted on genetically engineered micro-organism for the first time, nobody thought that biotechnology could manipulate either plant or animal or human being. Further, none thought of the need for evolving a comprehensive law on biotechnology for regulation. However, the progress and development in the field of biotechnology mandated a comprehensive legal framework for proper regulation, the result being various pronouncements of the law courts, legislations at municipal and conventions at international level. With the coming into being of the Trade Related Intellectual Property Rights (TRIPs) agreement, protection of various inventions of biotechnology and regulation of biotechnology has become a complete reality. This thesis gives an idea
about the genesis of biotechnology with its historical developments. Biotechnology has
developments. Biotechnology has developed in various generations at different point of
time. Its progress has been expanding in scope and significance. Today, there is no field
where the significance of biotechnology is not felt. Biotechnology has become part of
modern-day life. Having recognized the significance of biotechnology and its inventions,
there is a need to regulate it with proper means under the patent regime. The evolution of
patent law on biotechnology dates back to the 1960s and the 1970 when patents were
claimed on living beings. However, it was the decision of the US Supreme Court in the
Chakrabarty's case which laid the foundation for the patent law on biotechnology. Now
a complete and comprehensive frame work of patent law on biotechnology, is available
thanks to various court decisions followed by international agreements and municipal
legislations. This thesis attempts to probe into the evolution of biotechnology patent law.
There is no doubt that biotechnology inventions could be granted patent like any other
inventions. However, given the complexity of manipulating living beings, granting of
patent on biotech inventions is given much attention. Since an invention that involves
genetically modified living beings may not satisfy the regular requirements of patent, the
issue has become debatable,

It is evident that as compared to USA, the patent law of the United Kingdom and
Europe are conservative when it comes to granting patents regarding biotechnological
inventions. This basically stems from the fact that the United Kingdom along with
Europe preferably would want to stick to the notion of not wanting to grant patents which
would invoke mixed reactions from various sections of the community. The same
standpoint is taken by India which also shares the same feeling. The Indian Patent Law
too disallows the patenting of living subject matter but draws an exception for the
patentability of micro-organisms. This also implies that the Indian patent law is also
open to the patenting of genetic material and their products too, provided they fulfill the
criteria of patentability. However, the position of the Indian law differs from the laws in
UK in this respect that India does not allow the patenting of animals as whole too.
Accordingly, inventions relating to transgenic animals will not be allowed protection in
India.
It is quite apparent that the field of biotechnology is ever growing. However with the increasing innovations in the field it has become quite essential that adequate amount of protection is made available but at the same time respecting the constraints of the modern society.

Currently, India regulates only single gene products. So far, the only GM crop permitted for commercial cultivation in India is the Bt cotton, which is resistant to the boll worm. Similarly, countries such as Australia, China, Canada, New Zealand, Russia and Taiwan regulate products at the single trait level. In the US it is not mandatory to produce additional safety information on multiple trait products developed by conventional breeding if a single trait product is already approved and the traits are unrelated. In contrast, the European Union considers every stacked trait product as novel or unique, regardless of the status of the parent trait.

In the case of biotechnological inventions, it is in the interest of developing countries to argue for the narrowing of scope of patent protection. India is in stronger position to bargain with the powerful countries. It can take steps to exclude several important subject matters, like naturally occurring micro-organisms, even when isolated and purified, gene patents, etc., from the scope of patentability based on the grounds discussed early. It will help the country to align itself with the countries from Africa and Caribbean group better because they are opposed to providing patents for life forms.

It will also give a reinforcing influence to the negotiations going on in the forums of CBD, WIPO and WTO. This position is relevant to the task offered to the expert committee set up to deal with the question of patentability of micro-organisms and pharmaceutical substances including the products of biopharmaceutical substances including the products of biopharmaceutical industry. It is the larger public interest and longer-term interest of industry and nation that must guide the policymakers and lawmakers at this important moment.
A patent for an invention is a kind of industrial property. The term "intellectual Property" is also used which is perhaps more appropriate since an invention is a product of the intellect. Development of technology and improvements in industrial techniques, which are so essential for the economic welfare of human society, depend largely on the growth of inventions capable of industrial application. In order to encourage the creation and manufacture of new articles and improvements in existing articles or their manufacturing processes, a system of granting a limited monopoly to the inventors in return for the disclosure of the invention to the public has developed in almost all countries. This is the genesis of patent law.

The Indian patent system has more than a hundred years of history behind it. The Patent Act, 1970 which embodies the protection of patents in India is modeled largely on the lines of the patents Act, 1949 of the United Kingdom. It also embodies many principles recognized in the patent systems of other industrially advanced countries. The basic principles of patent law are broadly the same throughout the world; differences exist mainly in the details of each system. In this sense patent law has not only a national, but an international character.

Patent law in India is a form readily accessible and comprehensible to all persons who are directly or indirectly interested in the protection of inventions or their commercial exploitation, and in particular to inventors, industrialists, patent attorneys and lawyers. The subject is developed topic wise in a rational manner instead of the conventional way of writing a running commentary on the sections of the Act. Though the decisions of USA and UK are not binding on India, the analysis of various problems and the principles expounded in the course of determination of those problems contained therein will be of undoubted value in the solution of similar problems which may arise under the Indian Law. Courts in India have, in the past, while interpreting the provisions of the Patent and Designs Act, 1911, often followed with approving the principles contained in English decisions. Besides the present Act has adopted many important provisions of the U.K Patent Act, 1949, and has also given statutory recognition to many principles enunciated in decisions of British courts. India, because of many other factors
such as Industry, state policy, technology advancement and like such reasons we are not having much subject in India only after the amendment to Patents Acts, 1970 the doors were open for biotech industry so it is very relevant for the study of USA and EU cases.

Biotechnology has become a new and challenging technique for established industries and for specialist entrants. Biological resources may genetically manipulate at every level from the specific variety of a crop to the genus or species in order to make them according to required form. Engineering the biological resources may endanger the environmental manipulation and remain a cause of public anxiety, however much politicians may back manufacturers. Yet improvements in yield may be a great boon to poor countries, but with cloning like technologies giving scope for organ development by embryo research and stem cell research apprehends much danger than good. Because of advancement of the technology day-to-day with in the decade period a new subject was developed called bioinformatics which relates with the genomic data such as gene mapping (Human Genome Project, now extended to animals also...) by using giant computers and knowledge of the biological function or functions of individual genes.

The cost of biotechnological research is mostly very large and from early stages investors turned to IPRs and above all to the patent system in the hopes of underpinning their investment. Much of the work started in universities and public research institutes attracted the corporate attention and started developing research and development institutes with huge investments by keeping patenting system as a motivating factor. A long term aim, particularly for small ventures, is to be bought out by a major firm. In that process any patent holding is likely to be assessed for its potential rather than its achievement. Like wise, for those which attain stock exchange listing as a company, patents may well be read as important indicators, most speculators have a primitive notion of what IPRs are for and so exaggerate them as signs either of success or of failure. Now the rate of patent filing increased tremendously immediate stimulus of these shares may effect the national economy by speculation, these things require regulating in a proper way.
Under the patent system the fundamental division between theories of patent system is as strictly a mechanism for enhancing socio-economic functioning at a national, regional or global level, and a theory which retains some place for rewarding individual intellectual contribution. The first prefers the grant core rights to one person, however arbitrary that result may be, because of the unique efficiency of individual ownership as an incentive to realizing technological potential. The second is much readier to recognize comparative claims of contributors or to insist upon free exchange of information as part of a competitive environment unimpeded by the IPRs. Under these two basic aspects required to be examined basing on the past experience of centuries. First one concerns its limitation to the protection of inventions as distinct from discovery and the second turns to the exclusion from patentability of inventions which it would be contrary to public policy or morality to exploit commercially.

Commodification of knowledge tends towards a broad interpretation of "invention" at the expense of 'discovery'. Thus in medicinal chemistry, it became common to treat as patentable the disclosure of a novel organic molecule whose practical value lay purely as a research step. The compound could be claimed as an intermediate in the manufacture of other compounds which in turn might well prove to have direct medical uses even though these were not yet known.

Day by day technology keeps on improving and at the same time continuous research emerges with different techniques as research tools. They are deployed for studies which are not seeking any improvement of the method itself but are pursuing an independent line of inquiry for which the method is the accepted procedure. These methods are 'research tools' in the common usage of the term. Out of experience it is universally acceptable fact that for academic and research purposes there must be an exemption from patent protection. It is rightly mentioned that for patentability invention must sufficient industrial applicability, for commercial exploitation. Research tool if it fulfills the elements of invention then it can be allowed as invention and by the same time regulates with industrial application. While providing the balance of interest the subsequent researcher is free to undertake follow-on work within a reasonable broad
compass. If the second researcher brings out a new invention then they can come to the negotiation table both for cross-licensing with the first inventor.

Consumable foods such as tomato, potato, etc if genetically modified possess 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 to the needs of the society deserve to be protected.

Inventions, which are new, are patentable. A subject matter that was in existence in nature, which is not considered 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 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 possess certain desired features. The modification and incorporation of the process certain desired features. The modification and incorporation of the desired qualities into a living being is considered as constituting an inventive step.

The requirements of patentability are correlated in case of biotechnology inventions. An invention which is not a patentable subject matter cannot be patented though it satisfies all the other requirements of patentability. The fulfillment of inventive step correlates itself with the fulfillment of the requirement of novelty. The fact that existing living beings are modified through biotechnology is related to the requirement of both 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 an inventive steps. Further, inventive step is also elated 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 are identified, 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 cannot be described. The conception of the invention not only satisfies the requirement of inventive step but also helps in describing the invention.

Patents are granted on the fulfillment of the requirements of patentability. 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 the 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 biotechnology inventions. Further, in conducting search also expert assistance is taken by the patent office. Patent are granted for a term of twenty years on successful fulfillment of requirements and completion of procedures. Different states follow different methods in granting patents. The USA follows post-grant opposition wherein patent is granted first and later advertised to invite oppositions if any. Patent could be revoked on successful opposition.

The great 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 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 claiming 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, as defenses. On successful defense by the defendants on these 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 phenomenon. Compulsory licensing is an instrument in the hands of the owners failure to exploit the invention or in case of improper exploitation or when the invention is not available to the public at affordable prices any USA are against compulsory licensing of biotechnology inventions. The TRIPS agreement states that in 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.

The ethical and moral standards of society objects to modification and patenting of living beings. Almost all the religious groups are against patenting of living beings, but the same is not being 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 beings 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 this is against the dignity of living beings. Ethicists say that human beings cannot
take the life of other living beings for granted in modifying and owning the same. Further, they say that a small alteration in an existing living being does not render to totally new; hence it does not qualify for patenting.

Nevertheless, the developments in the field of biotechnology and its enormous utility are prone to undermine all ethical considerations. The approach is that ethics could be sacrificed in view 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. But there should 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 unethical. At present transgenic micro-organisms, plants, animals, and human genetic materials are patented overriding the ethical concerns. It can be said that on account of the potential benefits of the biotechnologically produced living beings ethics have been sacrificed.

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 highly immoral and unethical. Similarly 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 proceed 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 biotechnology. In case of transgenic human beings and human embryos-ethics outweigh potential benefits. But in the case of transgenic micro-organism, 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 raises 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.

Merits of Biotechnology

- Biotechnology is capable of producing high-yielding, pest-resisting and herbicide-resisting crops
- Application of biotechnology in animal husbandry resulted in animals with qualities such as high yield of milk, wool, flesh and fast growth
- Biotechnology produced innovative medicines, drugs, vaccines, cures, and surgical methods. It is possible to cure even hereditary diseases through biotechnological processes
- Biotechnologically produced animals could be used for testing new medicines, drugs, and vaccines prior to the use of the same for human beings.
- In the field of food and beverages the application of biotechnology resulted in consumable foods with high nutritional values.
- For the people who are in need of organs, biotechnology extends great help. Organs produced through biotechnology could be transformed to the needy.
- In the field of environment, biotechnology is promising to be helpful in combating pollution and in maintaining ecological balance.
- Infertile couples can have children through biotechnology-assisted reproduction.
- Through cloning animals, plants, and other species could be conserved and preserved in order to maintain biological diversity.

Demerits of biotechnology

The potential of biotechnology is undoubted but the other force 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 mass destruction. Micro-organisms with destructive qualities like heightened infection efficacy may cause danger to the living beings. Using such micro-organisms for mass destruction, as biological weapons, will have destructive impact.
Release of such micro-organism, 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 biosafety. Further, gross misuse of biotechnology may result in procuring 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 beings. The demerits and dangers of biotechnology could be summarized as follows:

- One important disadvantage of biotechnology is that it causes sufferings to animals in manipulating them.
- The results of many of the biotechnology methods and processes have no guarantee but are doubtful as the success rate of biotechnological methods like cloning is only 15 percent.
- The application of biotechnology may result in too much control of living beings and biological processes giving rise to health hazard in plants, animals, and human beings and also environmental risks.
- Suppressed or removed genes through biotechnology may result in mutation and extinction of genes disturbing ecological balance. Further, transferred genes may jump into other species, giving rise to unforeseen problems.
- The irregular release of genetically modified organisms into the environment may result in unforeseen and irreparable consequences.
- Biotechnology may be misused in producing biological weapons by using microorganisms like bacteria and viruses with destructive genes, which may release harmonious gases when expressed.
- The ethics and morality of biotechnology inventions are frequently questioned and vehemently opposed.

After a thorough study of biotechnology and law, particularly focusing on patenting of life, a few inferences could be drawn by the evaluation of the law relating to
patenting of biotechnology inventions and the investigation into the patentability of biotechnology inventions have resulted in a 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. Similarly the probe into the ethics involved in patenting biotechnology inventions resulted in specific findings. On the whole the findings can be summarized as follows

- 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.
- The judiciary, which was active in the evolution of biotech patent law, gave liberal and sometimes unforeseen interpretation of the law.
- The regular requirements under the existing patent law have been relaxed to extend patent protection to biotechnology inventions.
- The patent procedure, especially in India, is cumbersome. In the USA it takes one-and-a-half year to grant a patent; in Europe it takes three years; but in India it takes more than five years to grant a patent for which procedure requires to moderate.
- The enforcement mechanism of biotechnology patents is finding difficulty in disposing of biotechnology patents infringement suits, because of the complexity and technical nature of the biotechnology inventions.
- The provision for granting compulsory license 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.
- There is a possibility of misusing the potential of biotechnology in producing destructive biological weapons against social order.
- There is a possibility of producing a transgenic human being by abusing biotechnology in violation of public order and morality. Doubts exist that given the potential of the biotechnology transgenic human beings might already have been produced.
There is always some scope for improvement and there will always be a margin for developments. Likewise, the law relating to biotechnology and patenting of life could be strengthened and streamlined by adopting certain modifications. On the basis of the findings of research work the following suggestions can be made which, if adopted, will bring the existing law in turn with the latest developments in the field of biotechnology. The suggestions may be adopted for the proper regulation and management of biotechnology inventions.

Recommendations

- The fluctuating approach of the judiciary may be put to a break by removing ambiguity in laws with reference to the patenting of biotechnology inventions.
- As patenting of different biotechnology inventions is universally accepted except for transgenic human beings, the local laws may be modified and streamlined by providing for specific exclusions and prohibitions in the light of the ethical and moral standards of the society.
- A universal declaration or convention on the prohibition of transgenic human beings and cloning of human beings for reproductive purposes as a whole may be adopted.
- The time period for patent grants in India should be reduced. The procedure should be amended to grant patent at least within three years, by keeping in mind the dynamic nature of biotechnology where changes take place rapidly. Further, in case of pendency of any patent application for more than three years before the patent office, due to the reason of delay in the office or due to the pendency of opposition proceedings or due to the pendency of appeal proceedings, the domestic laws may be amended to adjust the patent period accordingly.
- Taking the complexities involved in the field of biotechnology and difficulty in processing and patenting of biotechnology inventions into consideration there should be an expert committee in the patent offices to assist and advise in assessing and evaluating the patent applications claiming biotechnology inventions.
• In the light of technical nature of the biotechnology inventions the enforcement mechanism may take assistance from expert committees in adjudicating and enforcing biotechnology inventions.

• 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 on the part of the member states on satisfaction of necessary conditions, such as public emergency or to meet the public interest.

• In view of the patent protection to biotechnology inventions and in respect 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 convention on Biological Diversity (CBD) specifically addressing safety in biotechnology research.

• Given the potential of biotechnology in producing biological weapons there can be an amendment to the CBD to prohibit misuse of biotechnology and production of biological weapons to guarantee ecological balance and biological diversity.