CHAPTER-7

CONCLUSION AND SUGGESTIONS

Based on the long duration research, the researcher concludes by giving the following details. The concept of patent on life forms is obviously prior to TRIPS Agreement. Due to the rapid development in the field of biotechnology, the dimension of ‘invention’ got a new facet. It is evident that genetically altered life forms became the patentable subject matter as inventions. Judicial systems in some countries ruled out the argument that life forms are products of nature and considered as mere discoveries. For biological processes, which to a certain extent “exist in nature”, the invention concept had to be somewhat extended in order to cover these types of inventions.

In Europe, the eligibility criteria in the biotechnological field have been firmly settled by the EC Directive, which confirms EPC case law on this point of law. On the other hand, US law has established that genetically modified living forms are patentable as composition matter i.e inventions. Furthermore, products of nature generally considered inventions when some human intervention has been necessary to make them as patentable subject-matter. In respect of establishing the legal meaning of “existing in nature”, the EPO Guidelines confine it within narrow limits so as only to cover the substances freely occurring in nature. The Guidelines settle the matter by declaring substances found in nature which must first be isolated from their surroundings, which can be properly characterized and which are new in the absolute sense of having no previously recognized existence, eligible per se for protection.

For human made microorganisms, the court observed that the legislative history of the Patent Act connotes that the patentable subject-matter includes “anything under the sun that is made by man”. It is very clear that Chakrabarty’s decision only opened the gate for patenting life forms, particularly patenting man-made or altered microorganisms. This first step obviously led to include plants, animals and human body parts under the cloud of patentable subject-matters. In Europe, after following the guidelines of Budapest Treaty the applicant has to
assure by irrevocable declaration to the culture collection that samples of the microorganisms will be released upon request at any time to authorities and courts involved in the patent granting procedure from the date of the first laying open or publication of the patent application. In addition applicant has to ensure that the microorganism is stored in a viable state in the culture collection, until an appropriate period after expiration of the patent. Thus, it is clear that product claims for the microorganism per se are patentable only if the inventor has disclosed a repeatable method for their reproduction. Isolation of the microorganism from a soil sample or an induced mutation or multiplication of a deposited sample of the microorganisms is not repeatable methods. This keeps microorganism which can be found in nature, free from patent and available to anybody.

In India, the grant of patent in respect of microorganism depends upon the regulations concerning the requirements for the deposition of microorganisms under the Budapest Treaty, of which India has become a member and accessibility of that microorganism from the depositories. Moreover, after the Domnico’s decision and based on the Patent Amendment Act microorganisms are patentable subject-matter in India. The Mashelkar Committee report also supported granting patent on genetically engineered microorganisms.

Furthermore, in respect of patent on plants, the US Congress enacted the Plant Patent Act in 1930 for the protection of sexually reproduced plants which the PTO administers. In enacting Plant Patent Act, the Congress recognized that the work of the plant breeders in aid of nature was a patentable invention under the general patent statutes. The Act provides the plant breeder patent protection to a single claimed plant with a unique characteristic either physiological or anatomical that can be cloned by grafts, buds or cuttings resulting in a new plant with the same characteristics. It is so evident that Congress enacted the PPA as an amendment to the general patent provision and it was not until promulgation of the UPTA of 1952 that the plant patent provisions were included as a separate chapter of 35 USC. Moreover the court explained that the Plant Variety Protection Act 1970, was merely the exception of the 1930 Act. The court reasoned that prior to the Act sexually as opposed to asexually reproduced plants were excluded from
patentability because they would not be reproduced true-to-type through seedlings. By this 1970 PVPA, this type of reproduction was considered as patentable subject-matter. In addition, in 2001, US Supreme Court confirmed and declared that plants are patentable subject-matter under 35 USC Sec. 101 after carefully and elaborately scrutinized PPA and PVPA.

The EPC stipulates that plants are not patentable subject-matter under Article 53(b). This Article reflected the fact that some of the member countries of the EC, which are member states of the UPOV Convention, had already stipulated a special law for the protection of new plant varieties in compliance with the provisions of UPOV. Currently, there is a system of protecting new plant varieties under the UPOV and in addition the breeder’s rights have been expanded and strengthened by the revised UPOV of 1991 in conformity with the advancement of new biotechnology. The Board of Appeal also had taken an affirmative stand on patenting new plants. Moreover, the Biotech Directive says that inventions which concerns plants or animals shall be patentable if the technical feasibility is not confined to a particular plant or animal variety. It also allows that patenting of plant genetic resources by stating that biological material which is isolated from its natural environment and produced by means of a technical process may be the subject of an invention even if it previously occurred in nature. Thus, it is clear that the position of EU in respect of patentability of plants is admired by the court as well as EC Directives.

In India, the Patent Act specifically excludes plants and animals in whole or any part thereof including seed varieties and species and essentially biological processes for production of plants and animals from the ambit of patent protection. As far as the Plant Variety Protection is concerned, India follows *sui generis* system by enacting Protection of Plant Varieties and Farmers Right Act 2001.

The researcher would also like to emphasize the fact that drawing a line between what is eligible for *sui generis* protection is quite difficult. The main reason for this issue is there is no effective and constructive harmonization between the international legal framework and domestic laws. Currently, countries
Conclusion & Suggestions

are taking their own footsteps in respect of determining patentability of plants and plant varieties by leaving international instruments as empty papers.

Furthermore, the rapid development towards considering all life forms as patentable subject-matter except human beings, results in patenting of transgenic animals. In spite of certain issues, animals are patented today that leads to access its patentability. The claims of the animal patents are extremely broad which indicates the lack of well-defined scope of this patent and are not supported by the description. Another significant issue is the crucial quality of animals like plants, that set them apart from other invention in their self-reproducing tendency. This distinguishing characteristic has raised many complex issues in extending the coverage of the patent statute to animals especially within the agricultural industry. All these factors raised doubt relating to the implication of these facts in the current existing patent system.

There are claims to the process for creating transgenic animals and this had already been determined and also the transgenic animal as a product is patentable which was decided in Harvard Mouse case. Now it is possible to build a farm of transgenic animals to which patent protection is offered. Thus, one small mouse sparked one of the largest advances of technology as we know it today.

In the US, it is obvious that transgenic animals can be patented as products-by-process, under Sec. 103(b) of the Patent Act, provides that the process of biotechnological processes fall within the scope of the patent on the process. Transgenic animals are subjectively considered as ‘manufacture’ or ‘composition of matter’ or the process it was modified. So, the patentability question of transgenic animals was well settled by the Judiciary by conveniently interpreting the Patent Act. In addition, the Congress proposed an Act known as Transgenic Animal Patent Reforms Act 1988, which provides for an exemption which allows farmers to reproduce patented transgenic farm animals through breeding for use in the farming operation or for sale. Most significantly, the farmers exemption does not apply, if the germ cells, the semen or the embryos of the patented transgenic animals are sold without the authorization of the patent owner, otherwise it amounts to infringement. Thus, it is clear that the Congress is not having much
interest in enforcing these proposed legal measures in order to avoid overlap between the Patent Act and the proposed Act.

In European Union also, transgenic animals can be patented as products and the process by which they are produced is also patentable. The EPO in a famous case concluded that Onco Mouse was not included in “animal variety” and did not fall in the exclusion under Art.53(b). Thus, it is clear that EU also followed the footsteps of US in respect of patenting transgenic animals.

India is concerned, under Indian Patent Act expressly excluded the patentability of transgenic animals, which says animals, plants or part there of not only of the natural origin but such living entities of artificial origin such as transgenic animals and plants or any part there of are also not patentable.

Thus, the researcher in this regard found that the existing legal provisions in relation to patenting transgenic animals are not clear either in domestic set up or an international arrangement.

In addition, the journey of the patent regime in granting monopoly reached the human biological materials within no time after the patenting of animals. It is quite evident that patents are granted to human cells, genes and DNA. These developments obviously require the utilization of human body parts, both for experiments and for transplantation. Based on Moore’s decision and Relaxin’s case it was found that the patent on human body parts was done without much judicial checkpoints. Currently the patent over human embryonic stem cells and cloning raises a lot of legal and ethical questions. It is further added that in respect of patent on human body parts no legislative frameworks existed in both international and national level, but the judiciary in US interpreted the patent law provisions in the context of its own understanding and economic utility of the country.

The researcher also finds that there is no conflict between TRIPS Agreement and Convention on Biological Diversity with respect to patenting life forms because both these important international instruments do not prevent extracting biological resources for industrial purposes through patent system. Particularly, Art. 27.1 of TRIPS Agreement requires Member States to provide patent protection for all types of invention irrespective of the field of technology.
Conclusion & Suggestions

This means, patent can be granted to the inventions ‘in all the field of technologies’. It also includes inventions in the field of biotechnology. In addition, the TRIPS Agreement does not define the term ‘invention’, as a result US like countries considerably expanded the scope of invention and included life forms created or manipulated or altered by man as patentable inventions. Thus, it is clear that the lack of a specific definition of invention means that the sole determining factor is whether the biological materials meet the granting criteria that it would appear is the sole basis of determining an invention. It can also be concluded that TRIPS Agreement obviously promoted the patentability of genetic materials including genetically modified organisms.

On the other hand, the Biodiversity Convention is one of the most ambitious attempts in any legal system to integrate environmental goals with a wide range of economic developments. It aims to conserve the earth’s plethora of biological resources from uncontrolled exploitation and destruction of biological resources including genetic resources. The global pressure to privatize biological resources, the CBD stands as an important watershed in international efforts to promotes biodiversity conservation. It also asserts that IPR must not conflict with the conservation and sustainable use of biodiversity. The researcher also finds that CBD allows exploitation of or accessibility of genetic resources, at the same time it imposes certain obligation upon the Member States in relation to conservation of biological diversity.

Significantly speaking, in respect of patent protection over biotechnology inventions, the TRIPS Agreement fails to create a single universal patent system. Moreover, CBD does not make any confrontation with TRIPS Agreement with respect to patentability of genetic resources through biotechnology.

The researcher further found that patent system insists the inventor of an invention i.e new life forms has to commercially exploit and bring the invention at the market place for utility. If the inventor fails to commercially exploit his invention, the Patent Office shall revoke the patent protection. As a result of this legal and economic compulsion, huge quantities of patented genetically modified life forms are already released into the earth and most particularly in the human
Conclusion & Suggestions

environment. This caused huge damage to the biodiversity including human beings.

It is proved that the introduction of GMOs into the environment affects the biodiversity in many ways. In this respect the researcher would like to focus on the following findings. The first one is the patenting on life forms are against the natural process. With the help of genetic engineering, the inventors are able to manipulate or alter nature’s own handiwork, it also destroys the nature’s order and structure. Taking gene from one animal and inserting it into other life species is absolutely against the God created nature.

Secondly, releasing huge quantity of GMOs into the environment severely endangers the ecosystem. In this argument the researcher questioned 100 respondents and 88% favoured this hypothesis and the remaining numbers did not accept the statement. Thus, the researcher concludes that GMOs adversely affect the ecosystem. For example, herbicide resistant genetically modified crops will destroy soil bacterium and other species and also once the harvest is completed, the toxic content inserted into the genetically modified crops always resides in the soil. It in fact causes heavy damage to the ecosystem.

Thirdly, it is found that the GMOs also created genetic contamination or pollution in the environment. Due to the natural process of cross-pollination the genetically modified characteristics of GMOs mixed with non-genetically modified crops and other species respectively. This obviously caused genetic contamination or pollution. This hypothesis also was tested and 82% of the respondents agreed to this statement. Hence, the researcher concludes that GMOs caused genetic contamination or genetic pollution in the biodiversity.

Fourthly, the deliberate release of GMOs into the environment created genetic erosion and genetic uniformity. The genetic erosion refers to the overall loss of plant genetic diversity resulting from the extinction of different plant varieties, the primary example in this context is the widespread use of monoculture in agriculture. In fact, it is a paradoxical situation in which modern plant breeding results in the destruction of the very genetic diversity it depends on. Moreover, the related problem of genetic uniformity arises when many individual plants in a
Conclusion & Suggestions

Single crop have common parents and as a result vary in similar genetic composition. The widespread cultivation of improved cross-bred variety is the primary cause of genetic uniformity. The researcher tested the hypothesis of GMOs lead to monoculture in agriculture, was favourably responded by 78% respondents. In addition, 76% of the respondents opined that GMOs positively leads to genetic erosion. Thus, the researcher concludes that GMOs in fact lead to genetic erosion in the biodiversity.

Fifthly, the deliberate release of GMOs into the environment destroyed beneficial non-target insects and aquatic life forms. The best example for this argument is the considerable extinction of Monarch Butterfly because of cultivating Bt in-built pesticide crops. This hypothesis is also tested by the researcher. Almost 70% of the respondents opined that GMO leads to extinction of beneficial insects and 60% of the respondents agreed to the fact that GMOs destroy aquatic life forms also. Thus, the researcher concludes that GMOs leads to extinction of beneficial non-target species and aquatic life forms in the biodiversity.

In addition, the GMOs also created super-weeds that obviously caused huge destruction in the biodiversity. Around 69% of the respondents agreed to this statement. Moreover, 80% of the respondents opined that GMOs also lead to habitat changes of all kinds of species in the environment. Almost 52% of the respondents favoured the statement that the GMOs also caused reduction of wet lands in the earth. Most significantly, 76% of the respondents accepted the argument that deliberate release of GMOs into the environment affected the common heritage of mankind.

Introduction of huge quantity of GMOs into the environment induced climate change. The researcher tested this hypothesis also and 62% of the respondents agreed to this statement. Thus, the researcher concludes that all the above discussed factors endangered the natural biodiversity, as a result global warming is increased and which ultimately induced climate change.

In respect of agricultural sector, due to the advent of genetic engineering, lot of changes had taken place including cultivation process and using genetically
modified seed varieties in the farm-lands. The new genetically modified seed varieties are having different kinds of characteristics like herbicide tolerant, in-built weedicide seeds, BT crops etc. This GM crops in fact undermine sustainable agriculture and it completely replaces the traditional methods of agricultural practices.

It is further noted that patent on transgenic crops caused utmost hardships to the farmers. Firstly, the farmers cannot save their own crops for cultivation and secondly, the patent on transgenic seeds are preventing the farmers from saving seeds for replanting unless they pay the royalties to the seed companies. In fact the seed monopoly will severely threaten the livelihood of farmers all over the world. In order to possess monopoly over the seeds, currently the seed companies are using Technology User Agreement. This will obviously affect the vulnerable farmers in many ways. Based on this agreement, the seed companies can make periodical inspection upon the farm-lands belonging to the innocent local farmers. It indeed results in biocolonization. More so, if patented GM crops and its resisting character mixed with non-GM crops, the owner of non-GM crops will face patent Infringement threat. This will affect the inherent right of the farmers because if any changes had taken place in his own farm-lands, he had every right to control it but the seed company is showing its upper hand over the native farmer. This indeed makes huge adverse impact upon the indigenous farmers.

In addition, the widespread use of Terminator Technology will vehemently affect the farmer’s interest. This technology is the form of genetic engineering that inactivates a plant’s ability to reproduce or germinate by making its seeds infertile. Thus, the patent on Terminator Technology- based crops leads to extinction of all natural seed varieties and the researcher tested this hypothesis. Almost 86% of the respondents favoured this statement. Hence, the researcher concludes that using Terminator Technology is very dangerous to the natural seed varieties and entire agricultural sectors too.

It is also concluded that patent over some kinds of staple crops will severely affect the food security. In respect of cultivation and the harvest, the seed industries are taking control over the farmers and restrict free flow of food
production. This will also make heavy burden upon developing and least developed countries as well. Hence, it is found that patent on GM crops will never ensure food security and in this respect around 80% of the respondents agreed to this statement.

It is also found that the GMOs are created mainly for humans and animals. As a result of this, plenty of GM foods are flooding in the market place all over the world. It is true that the GM foods are available even in non-GM cultivation countries. GM foods in fact caused many health risks to both humans and animals. Many of the respondents favoured the following allegations. The first one is GM food and BT crops caused allergencity to both the farmers and the consumers. Secondly, GM food gradually creates cancer risks to the human beings. Thirdly, like crops GM foods create antibiotic resistance to the human being. It really made many problems to the cells and genes of the human body. Fourthly, it causes viral disease and birth defects to the human beings and animals. Hence, the researcher concludes that GM foods are positively caused risk to the human and animal health.

It is well proved that the deliberate release of GMOs into the earth causes many social and environmental issues. Most importantly, it is found that GMOs destroy biodiversity, as a consequence of this, global warming is increasing day by day that obviously leads to climate change. Currently, climate change is a highly burning issue and the demography is becoming severe victim and the level of greenhouse gas is also increased because of new type of agricultural practices. In this regard, the researcher would like to emphasize the fact that biotechnology based agricultural practice is the dangerous culprit. Thus, based on this research it is concluded that the deliberate release of huge quantity of GMOs into the earth really caused and is really causing climate change. In addition, it is noted that as far as international instruments in respect of climate change is concerned GMOs are not a subject-matter and is not sufficiently and actively addressed.

All these above discussed issues are happening without adequate legal solution either in the international level or in the domestic level. In respect of the international arrangement the CBD requires the signatories to identify processes
and categories of activities that have or likely to have significant adverse effects on conservation and sustainable use of natural resources. It also requires countries to be able to control any living modified organisms, so that they do not present a hazard to the environment or human health. The CBD imposes obligations upon the member countries to conserve natural resources through both in situ and ex situ methods by establishing some administrative tasks. It is found that the provisions of CBD do not positively operate on the deliberate release of GMOs into the environment.

Cartagena protocol on biosafety is the main international; legal instrument addressing issues related to the introduction of GMOs into the environment. The protocol clearly acknowledges the need to create standards for biosafety to control the potential effects of biotechnology on the global environment. Ironically, the Preamble recognizes both sides of the policy debates concerning biotechnology and the importance of free international trade. The primary objectives of the protocol is to ensure an adequate level of protection for the safe transfer, handling and use of living modified organisms derived from modern biotechnology. It is also found that the Cartagena protocol is an environmental treaty by virtue of the fact it addresses the potential impact of the introduction of living modified organisms into the environment. However, while the protocol is an environmental treaty, it is also an international trade agreement in so far as it mainly seeks to regulate trade in living modified organisms. Thus, it clearly shows the fact that Cartagena protocol facilitates free flow of the trade of GMOs but it completely failed to establish liability regime within the ambit of the protocol.

Furthermore, the supplementary protocol to Cartagena protocol on biosafety, i.e. Nagoya protocol on Kuala Lumpur meet in 2010 aims to contribute to the conservation and sustainable use of biodiversity by providing international rules and procedures for liability and redress in the event of damage resulting from living modified organisms. The protocol reaffirms the precautionary approach contained in the Rio Declaration of Environment and Development. It is really a welcome step. In addition, the protocol takes an administrative approach whereby response measures are required of the operator or the competent authority if the operator is unable to take response measures. But this supplementary protocol also
failed to make or address what kind of civil liability is most appropriate in case of damage to an individual stakeholder or the community as a whole. Moreover, it does not effectively require the member states to take measures in respect of environmental damage due to the release of GMOs into the environment.

In the issue of the introduction or deliberate release of GMOs into the environment, it is found that there is no scientifically sound risk assessment mechanisms either in developed countries or developing countries. As per the existing system, the scientists must rely upon both laboratory experiment and limited field studies for the evaluations. Scientists have only very recently started to suggest standardized tools for evaluating the health risks of GMOs.

In addition, in order to protect the environment the precautionary approach shall be widely applied by the States according to their capabilities for the threat of serious or irreversible damage. Lack of scientific certainty shall not be used as a reason for postponing cost effective measures to prevent environmental degradation. In fact the GMO cultivating countries are not bothered about this precautionary approach, instead, they are trying to improve their trade in relation with GM products.

It is further found that current regulation in the United States reflects the passive attitude of the regulation of GMOs. This shows that US is not ready to take stringent legal measures to regulate the release of GMOs and to monitor the adverse impact happening in respect of such release. As US wants to capture the entire biotechnology market, the Patent Office is granting patent to all kinds of GMOs. This really made a huge threat to the human environment including the health of human and animal beings. The US is also a country to export large quantity of GMOs to other countries, so that it does not bother about the adverse implications and it treated GM products and non-GM products as equal.

In respect of the regulatory mechanism, the European Union has made some welcome steps. Most particularly, the EC Directive provides a common regulatory framework in the Member States to protect human health and the environment when deliberately releasing GMOs into the environment. This stresses upon applying the precautionary principle and establishing environmental
Conclusion & Suggestions

risk assessment. Moreover, the Directive refers to the principle of sustainable development and the polluter pays principle. But the Directive does not apply to cases of personal injury, damage to private property or to any economic loss. In addition, the EC Directive imposed a duty upon the industry to label their GM foods before bringing them into the market, but it also failed to make effective liability mechanisms in respect of injury caused. Even though, comparatively, EC regulatory mechanisms in case of deliberate release of GMOs into the environment is rather effective than the US system.

The government has established certain committees to regulate the release and handling of GMOs into the environment, and formulated some rules and regulations to govern the release and use of GMOs in India. Though, the safety mechanisms are made by the government of India, still it failed to enact a comprehensive legislation so as to regulate the deliberate release of GMOs and using the GM food and feed products at the market place. Moreover, all these rules and regulations made by the government literally failed to address liability mechanisms in case of injury caused to humans as well as to the environment. Despite, the protests all over the country and the Supreme Court instructions to the government, the government is still allowing BT cotton and BT brinjal for cultivation. Hence, it is found that India has failed to make appropriate legal measures to regulate the release and use of GMOs into the human environment.

Finally, it is concluded that in case of injury, the States can apply for civil liability based on common law principles of tortious liability including strict liability, tort of trespass to land and nuisance. For the environmental pollution, States can apply polluter pays principle in order to repair the damage caused to the environment.

SUGGESTIONS

Based on the research, the researcher would like to propose the following suggestions;

1. Patent shall not be granted for plants, animals and human body parts and in respect of microorganisms, the patent can be given only in relation with pharmaceutical products.
2. The international community should formulate a universal patent system upon life forms and it should make stringent rules regarding patentability criteria in terms of ensuring human health and environmental protection. Moreover the states should ensure the fact that the patentable subject-matter will not affect human health and biodiversity and the Patent Office shall issue patent only after receiving laboratory and field experimental report from the inventor in respect of biotechnology based inventions.

3. An international regulations to Genetically Modified Organisms shall be drafted with mandatory minimum standards in accordance with consensus of all the TRIPS Member States. Thus, there should be a uniform regulatory mechanism concerning the determination of liability and redress.

4. TRIPS Member Countries should be required to establish highly equipped laboratories and to create “scientifically sound risk assessment system based on information infrastructural capabilities” to create public awareness.

5. All Genetically Modified food products should be labeled and to monitor this issue, an administrative authority should be established both in the international and regional levels.

6. An effective and comprehensive legislation should be enacted by the competent authorities so as to allow, monitor and restrict the deliberate release of Genetically Modified Organisms into the environment. Moreover the legislation should also cover the standards for fixing liability in case of personal injury, damage to the property and damage to biodiversity. The legislation should also facilitate the injured person to seek both civil as well as criminal remedies from the wrongdoer.

7. Finally, India should enact Genetic Pollution Liability and Redress Act in order to avoid hardships because of allowing BT cotton and BT brinjal within our territory.