Patenting Biotechnological Inventions: Social, Legal and Ethical Issues

Dr.FaizanurRahman
Lecturer
Nehru Memorial Law PG College, Hanumangarh Town (Raj.) 335513

Abstract

The biotechnology revolution is gaining momentum all around the world. Biotechnology functions like a fruit on a tree having roots of biological sciences, microbiology, genetics, molecular biology and biochemistry and trunk of chemical engineering. So, it is indeed difficult to define the precise scope and extent of the applications of biotechnology. The introduction of biotechnology to produce new products or molecules poses various challenges, which may be technical or ethical. The biotechnology sector, unlike the information technology sector is highly regulated.

Intellectual property is the most valuable asset of a biotechnology company and the most important intellectual property rights relating to biotechnology companies tend to be patents. India has tremendous potential in the biotechnology sector, but one of the significant hurdles facing the industry is the current legal and regulatory framework. In modern biotechnology, patents are a controversial issue and are more interesting for the public than any other technical field. Advances in biotechnology are bound up in ethical, religious, political and legal issues.

The present research paper focus to the moral and ethical issues brought about by the patenting of living organisms and the difficulties experienced by the patent laws in responding to the intricacies posed by the ethical side of biotechnological inventions. It explores the ethical and political controversy over patents relating to stem cell research, so called therapeutic cloning and human cloning. It also presents a critical 'triptych' exploring interaction of biotechnology, ethics and patent law. It in general gives the conceptual issues in patenting the biotechnological inventions.

Keywords: Genetic Engineering, DNA Sequence, Bioethics, Ordre Public, Biotechnological Inventions, Patents, Morality

Introduction

The last 50 years have seen an increasing emphasis on ethical, moral, social, legal, political and economic implications of science. Biotechnology has been no exception to this trend. The inventions of biotechnology are viewed as against the moral and ethical considerations of the society, as these inventions involve tinkering with life as well as monopoly over life. Societal concerns state that life is not patentable and living beings should not become a subject of patent monopoly. However, with the emergence of biotechnology capable of producing non-natural living beings, patenting of living beings or life gained significance in modern era.

The moral controversies surrounding biotech inventions stem from several concerns including those arising from the mixing of human and animal species, the perceived denigration of human dignity, the destruction of human life, the exploitation of women for their eggs, and the

concept of ownership of humans. Biotechnology continues to offer considerable potential for enhancing human health and well-being. Effectively applied, modern biotechnology may contribute to economic growth, technological development and human welfare. Yet it has also raised concerns about ethical and moral issues, equitable sharing of the benefits of biotechnology, environmental impact, the accelerated pace of change and the regulatory challenges. Just as the impact of modern biotechnology is beginning to be felt, there is increasing recognition of the importance of a balanced IP system in assuring economic development. Many countries are currently building IP issues into their economic, industrial and technological planning, and into research and education programs.

The use of recombinant DNA to modify the genetic structure of plants, animals and microbes and the ability to clone adult cells from mammals jointly contribute to an international controversy that has several axes of contention. While theologians and philosophers have thus far focused primarily on applications in the field of human medical science, the broader public has arguably been equally (if not more) concerned with the use of these techniques in food and agriculture. This popular concern with biotechnology is both prudential and moral. There are worries that the technology may have unknown and unacceptable risks, but there is also apprehension about the ethics of this seemingly new and radical activity. Furthermore, risks can be readily converted into moral concerns.

Patenting of new inventions require proof of novelty, inventive step or non-obviousness and disclosure of invention. But in biotechnology inventions the basic subject-matter is something already existing in nature. It is a well-accepted principle that in patent law naturally available subject matter is excluded from patenting on the ground that it contributes nothing new. So in biotech invention, the productivity of this material was considered as natural, converting them into private property has been considered unethical and against public interest. In addition to this, it also raises moral and ethical issues like playing God by human beings and degrading Gods creation to mere material objects by making it private property using the advanced techniques. Also test of obviousness/inventive faculty in patent law created difficulties in granting biotech patent for biotech inventions. Another problem involved is the practical requirement of written description of invention and the production of samples. However, developments in biotechnology resulted in finding solution for these issues.

Biotechnology and genetic engineering, as well as any other form of research involved with genetic material, and especially with the genetic material of human beings, has always given rise to intriguing questions for legal scholars. In early days there was the Genentech case, which dealt with recombinant DNA technology and gave rise to complex discussions, but this was still primarily a case on patent law and one that was dealt with by patent lawyers. Then the discussion moved on to include ethical, moral and environmental issues by the time cases Onco-mouseandPlant Genetic Systems came around. Animals and plants were involved and that raised the stakes. And now we have reached even more sensitive levels, because technology has moved on to cloning and the idea of cloning of human being and work with embryonic stem cells has been burned into the consciousness of society. Intellectual property rights for biotechnological inventions also raise related but quite distinct sets of issues concerning equity. Northern firms are accused of pirating and patenting biological material and traditional knowledge from the gene-rich developing world for profit, without fair and equitable sharing of benefits or the appropriate transfer of the new technologies. TRIPs deals with ethical and moral aspects of biotechnology or bio safety by allowing under Article 27.2 patent exclusions of inventions 'the prevention within their territory of the commercial exploitation of

which is necessary to protect *order public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to environment'.

Areas in Biotechnology that Raise Ethical and Related Questions

Areas that have major ethical, moral, social, political and legal implications are the following:

a) Genetic engineering,
b) Tissue culture,
c) New materials such as bio pesticides,
d) Gene therapy,
e) Stem cells,
f) Plant-based drug formulations,
g) Organ transplantation,
h) Bioinformatics,
i) DNA fingerprinting, cloning, and
j) Biological weapons.

These areas can be classified into four groups:

(i) Agriculture,
(ii) Medical and health care,
(iii) Reproduction, and
(iv) Defence.

In each case, we have one or more of the following possibilities:

a) Immense gain for mankind at large, but raising major ethical concerns.
b) Intra-country exploitation through unethical practices, thus underscoring the need for the country to have appropriate regulatory mechanisms;
c) Inter-country exploitation which encourages and propagates neo-colonialism; and explicit and manifest damage to plants, animals and/or human beings, and to the environment.

Patenting of Biotechnology Material: The Emerging Issues and Challenges

The issue of patenting life or animate organisms and living cells, tissues is more challenging than the simple task of enacting legislation and statutes. The issue has, at its heart, a conflict of interests, ideas, notions and paradigms. The patenting of biotechnological inventions remains a controversial issue. There are multiple factors responsible for the controversies in biotechnological patents. Some of the key issues and challenges before the patenting regime in relation to the field of biotechnology include:

1. In the case of biotechnology the patentability criteria-novelty, utility and non-obviousness for granting a patent, has been throwing open new challenges in the form of identifying the novelty in the living matters, which is a very difficult task, if not impossible. This is because, the living things like, animals and gene sequences exist naturally, and as some rightly argue it is impossible for such living matter to be novel.
2. Obviousness has been a sticky subject in the realm of biotechnology because scientists use similar techniques to isolate different gene sequences.
3. It is claimed that the standard of utility has been elevated for biotechnological innovations. In most technologies, the utility standard is considered de minims. However, because many of the innovations in biotechnology seem 'unbelievable', patents have sometimes been refused for lack of utility.

4. **Patenting of Human Genome:** Patenting of human genome demands great concern. The most common objection to this type of patent is that human genes occur, naturally, they are there to be discovered and not invented. Gene patenting raises two opposing questions:
   (i) Is it ethically permissible to patent segments of the human genome when the segment represents part of humankind's 'natural' or universal heritage?
   (ii) Is it unethical to deny patenting of human genome given the vast economic resources and human effort?
5. **Conflict between TRIPs and Convention on Biological Diversity (CBD)**:
   It is pertinent to note that, at the international level, there is a conflict between TRIPs and the CBD. The former compels patent coverage on the genetic materials while latter recognizes sovereignty over genetic resources. Thus, the issue of protection of biological diversity and its conservation vis-à-vis the patenting regime in the field of biotechnology is bound to raise crucial issues pertaining to human rights etc.
6. Unique features of new technologies can result in difficult questions of interpretation for patent law. In modern biotechnology, the distinction between discovery and invention is becoming blurred. Moreover, genetically modified organisms (GMOs) are unique as inventions. Not only are some of them alive, but also they are able to reproduce on their own, and are not well standardized, easily described and so on. If they are released into the environment, they will interact with it unpredictably.
7. It should be noted that, the least developed countries are rich in genetic resources, and many object to intellectual property laws and alleged 'biopiracy' on the grounds of morality and social justice. Thus the moral debate over life patenting has become increasingly important to discussions of international trade and international justice.
8. The TRIPs agreement has not defined microorganisms and microbiological processes. This leads to doubts as to whether the micro-organisms existing freely are patentable or their mere isolation in pure form are patentable or human intervention in establishing a level of novelty in the discovered micro-organism is needed for patenting. This also leads to the question as to whether a product produced by a microorganism which is known, can be patentable or the process is patentable. In absence of clear definition of microorganism and micro-biological process in the TRIPs agreement, the country needs to draw a distinctive line between the product of human intervention leading to novelty and those freely occurring in nature.
9. In the area of biotechnology, there are further debates and issues on the right to patent living organisms, especially resources and seeds that have been developed or passed on as traditional and public knowledge. This capitalization on public knowledge often comes onto conflict with indigenous knowledge and the right of indigenous people, sustainability of local ecosystems, and even the ability of protection of the global environment. As a result, this has also raised many philosophical questions.
10. The food sector in the country will also have to face new challenges in the new patent regime. Different processes and products will become patentable.
11. The current patent system may not provide adequate property protection for biotechnological inventions. This is for the reasons, that genetically engineered inventions are too complex to be accurately described, making it difficult to determine whether the invention is patentable or infringing and that the complex of organisms inhibits disclosure of inventions that would enable the public to make and use the invention after the patent expires.

12. In the case of biotechnological patents, there is a great possibility of granting benefit of patent to an undeserving patentee because sometime the intricacies involved in this technology make it possible to grant patens on gene fragments, genetic tests and proteins where the real functioning is not fully known.

The fears associated with the products of biotechnology are not so much because of the product but because of the emerging IPR regime and control of intellectual property by the MNCs.

Legal Issues

Legal problem to patenting of life form is centred on whether or not under existing criteria of patentability, life forms may be patented. In US, until 1980s legal interpretation has denied the eligibility of all life form for patent rights because it considered such inventions as mere discovery of unknown things in nature. This was reflected in the decision in Funk Bros v. Kalo Inoculant Co. In this case, the claim was for a patent for mixed culture of Rhizobia capable of inoculating seeds of a plants belonging to several cross inoculation groups. Here, the Court held that "he who discovers a hither of unknown phenomenon of nature has no claim to a monopoly of it which the law recognizes. If there is to be invention from such a discovery, it must come from the application of law of nature to a new and useful end. Even though it may have been the product of skill, it certainly was not product of invention."

However, it created a major difficulty to draw a line between discovery and invention especially when DNA technique has been developed to isolate genetic materials. Following the Chakraburty's decision the US patent office even granted patent for Oncomouse for studying cancer drug. The only criterion was human intervention and they never looked into the issue of morality or public Order.

The conflicts between science and the law are centuries old and have greatly intensified with the rapid progress that has shaped our world into one which relies on technology to make our lives more efficient and which promises a better tomorrow for everyone. In the early days, science and law came into conflict because scientific theories and the prevailing concepts of law were immeasurably divergent. The conflict we face in this day and age is not whether scientific postulates that are contrary to rule of law should prevail, but is more of a decision on the extent to which law, or government, should or should not influence scientific progress. The law is no longer stagnant and is incessantly attempting to stay abreast with the rapid pace of progress and development. Man, in his need to keep society under control will continue to strive towards establishing a balance between the extremes of scientific innovation and the established rules of law.

The biotechnology industry has come of age and has led to nearly infinite prospects such as tailoring treatments to people's individual genetic makeup, developing new vaccines and preventing disease by intervening in the genome. The biotechnology industry has certain unique aspects that distinguish it from other sectors, such as lengthy product development lifecycles, significant financial resources, complex intellectual property (IP) issues and the need for partnerships for manufacturing and marketing purposes. The scientific advances have brought along with them a multitude of controversial legal issues that require a multidisciplinary approach, to arrive at a possible solution. The powerful benefits that arise from biotechnology carry with it a tremendous responsibility. The rapid progress in cutting edge areas of biotechnology research in recent years has led to widespread discussions on the

need to frame appropriate laws to maximize the benefits of new technology, without compromising on ethics. Some of the significant areas of concern have been outlined herein below:

(i) Human Cloning

The word "cloning" refers to a large class of reproductive technologies performed in laboratory, industrial and even household settings. Home gardeners who propagate plants with cuttings are performing a rudimentary form of cloning. The biological fact common to all forms of cloning is that the new organism or cell has the same genetic make-up, the same DNA, as the original organism or cell from which it was cloned. Cloning Technology allows us to generate a population of genetically identical molecules, cells, plants or animals. Because cloning technology can be used to produce molecules, cells, plants and some animals, its applications are extraordinarily broad.

In 1997, the entire world was shocked and captivated by the news that a cloned sheep called Dolly was brought into the world by a nuclear transfer of somatic cells. These concerns were not about Dolly, the now famous sheep, or even about the considerable impact that cloning may have on the animal breeding industry, but rather about the possibility of cloning humans. The ethical concerns about human clones involve the risks and uncertainties associated with the current state of cloning technology. This technology has not yet been tested with human subjects, and scientists cannot rule out the possibility of mutation or other biological damage.

There exist numerous controversial issues involved with human cloning such as the possibility of deformed offspring, designer babies and the rights and legal protection for cloned humans. Further, concerns have been expressed regarding the possibility of premature aging of clones, especially since Dolly, the sheep contracted arthritis at an early age and scientists are yet to determine whether it was caused due to genetic defects. Human cloning is certain to have novel and profound legal ramifications on many non-medical aspects of society. The concerns about cloning do not arise from the nature of clone itself, but from the effects upon the clones, and upon society, of turning the parent child relationship into that of manufacturer to product. Religious scholars from a wide range of faith traditions have contributed to a substantive and remarkably diverse literature on the ethics of human cloning.

However, on the other hand there exist concerns in certain scientific communities that the extent of legislation against human cloning might result in stifling research into human embryology that could lead to new treatments for disease. The potential benefits include the use of cloning by infertile couples wanting to create a genetically related child or those wishing to clone a lost loved one. It has been said that often the change in custom or practice in an emotionally charged area has always elicited a response from established custom and law of horrified negation at first; then negation without horror, then slow and gradual curiosity, study, evaluation, and finally a very slow but steady acceptance. Many people viewed the birth of Louise Brown in 1978 as an aberrant and abhorrent event. Yet she was just the first of some 250,000 people conceived in the past 20 years through test-tube fertilization.

Countries worldwide have reacted to the prospect of human cloning by lobbying for a ban on the creation of human clones. Representatives of several member countries of the Council of Europe have signed a protocol that would commit their countries to ban by law "any intervention seeking to create human beings genetically identical to another human being, whether living or dead." The US House of representatives, on July 31, 2001 voted for a ban on human cloning. Further, the United Kingdom recently passed a legislation to ban reproductive

cloning. However, therapeutic cloning using cell nuclear replacement for research is not covered under the ban.

We cannot "undiscover" what is discovered; neither can we "uninvent" what has been invented. Developments in the field of biotechnology have shed light upon the fact, that the day when a human can be cloned is not as incredible or far off as it seemed. Until then we have time, but it is essential for society to be ready, educated, and open minded, so the law can act as required.

(ii) The Human Genome Project (HGP)

The completion of the human genome project, and the sequencing of other organisms' DNA, is widely regarded as a turning point in biology and medicine. The elaboration of the human genome sequence is a major step in demystifying the evolution of the human species and the workings of the human body. The possibilities that may result from the HGP seem endless. Geneticists are now able to identify genes that control diseases, aging, and other specific traits. This enhances the opportunity for the human race to rid itself of disease and unwanted genetic traits. However, The HGP has generated widespread interest in a large spectrum of questions regarding the ethical, legal, and social implications of the existence and use of human genetic sequences.

There exists fears' regarding the privacy and confidentiality of genetic information, including questions of ownership and control of genetic information, and consent to disclosure and use of genetic information; these fears stem from issues such privacy associated with medical information, which is currently a controversial subject. With genetic information being added to the information into medical files, there exist fears that such information could fall in the wrong hands. For example if a health organization is paying for the gene tests, and holds the view that it owns the information, it could be used to serve its corporate interests. There also exist questions regarding the right of third parties such as employers subjecting individuals to genetic testing to determine the likely future health status of the employee and insurers securing a detailed genetic profile of the insured. Insurance Companies can grant or deny medical insurance if they know the possibility of a client having a genetic disease. While this may help the insurance company save money but at the same time it is denying the client insurance coverage and proper medical treatment.

The HGP has also led to certain concerns regarding human rights. The new ability to transform life that has resulted from advances in human reproduction and knowledge in the field of genetics led to the Universal Declaration on the Human Genome and Human Rights. This was adopted unanimously and by acclamation by the General Conference of UNESCO at its 29th session on November 11, 1997. It is the first universal instrument in the field of biology. The uncontested merit of this text resides in the balance it strikes between safeguarding respect for human rights and fundamental freedoms and the need to ensure freedom of research. The Declaration states that no one shall be subjected to discrimination based on genetic characteristics that is intended to infringe or has the effect of infringing human rights, fundamental freedoms and human dignity.

There is an urgent need to develop programs directed toward understanding the ethical, legal, and social implications of HGP data, to identify and define the major issues and develop initial policy options to address them.

(iii) Stem Cell Research

A stem cell is a primitive type of cell that can be coaxed into developing into most of the 220 types of cells found in the human body (e.g. blood cells, heart cells, brain cells, etc). Some researchers regard them as offering the greatest potential for the alleviation of human suffering since the development of antibiotics.

Stem cells can be obtained from adults, but the stem cells that most researchers consider most promising come from embryos. Medical researchers hope to use stem cells to produce perfectly matched tissues to replace or repair organs that have stopped functioning, thus treating diseases including diabetes, heart problems and Parkinson's, and perhaps allowing the replacement of body parts. The concerns regarding stem cell research do not exist in researching these special cells, but the method by which researchers obtain the stem cells from embryos. The only way to harvest the cells is by killing the embryo. Those who believe that all human embryonic cells are human lives consider it immoral and unethical to use them in research. A viable alternative might be to use adult stem cells, taken from bone marrow or the brains of cadavers. Unfortunately, they are difficult to remove, are severely limited in quantity, and some experts say that they do not show the same promise that embryonic stem cells do. The potential benefits for this research are abundant but there exists a debate arising from differences in deeply held religious and philosophic views which give rise to the conflict between ethics and science.

Social Issues

Part of the implied social logic of technological innovation is that increasing the efficiency of production practices is generally, if not inherently, beneficial to society. Nevertheless, technology is a concern for social justice when specific products affect the distribution of economic rewards (and penalties) throughout society, or when less tangible social goods such as social cohesion or social legitimacy are damaged. Such impacts have been widely associated with biotechnology.

In common Law no one can claim property rights in human body or parts of human body like organs because of the social and ethical concerns prevailed in their society. The emerging patent claims for genetic material compelled the passing of a Directive on Biotechnological inventions in 1998. The Directives contains provisions defining Biotechnological inventions, Biological process etc. and what should not be patented-like cloning of human beings, use of human embryos for industrial and commercial purposes, modifying the genetic identity of humans etc and only the processes that lead to their discovery and isolation can be patented. Another speciality in the Directive is the European Union ethics panel where the patent office can seek advice on the ordre public and morality issues involved in the patent claims. Since the directive was passed, social activists have mounted many successful challenges in Europe against biotech patents, including patents on stem cell lines and various genetically engineered plants.

Social consequences are associated with all agricultural technologies. Some consequences, such as the elimination of hand labour jobs, may be intentional. Some technologies are too costly for poor producers, but can give large or wealthy farmers significant advantages over the poor. The economic structure of agriculture in both developed and developing countries means that aggressive early adopting farmers derive short-term benefits from production enhancing technology, but that the ultimate beneficiaries are food consumers. Although animal biotechnologies may be less susceptible to a farm size bias than are mechanical and chemical

technologies, it is reasonable to think that many poor producers will be unable to compete with richer competitors as a direct result of biotechnology.

The social concerns surrounding the use of transgenic technology:
The following are some of the most frequently raised objections:

(i) Biotechnology is "unnatural" and against the will of God.
(ii) Biotechnology will aggravate the prosperity gap between the north and south and will increase inequalities in the distribution of income and wealth.

Three particular issues are:

(i) There is an unequal distribution of funding for biotechnology between the public and private sectors.
(ii) Access to biotechnology will be challenging for resource-poor farmers, as it has proved with more traditional inputs such as seed, fertilizer and pesticides.
(iii) Biotechnology innovations may compete with traditional developing-country agricultural exports, as was the case with high-fructose corn syrup (produced using a biotech-derived enzyme) versus traditional sugar exports.

Resolution of these issues will depend in part upon how questions of equitable access to and funding of biotechnology are addressed. They are not, however, issues unique to biotechnology.

Farmers around the world have played a distinctly important role in debates about the effects of engineered organisms on nature and society. In India, hundreds of thousands of farmers have demonstrated against the corporate ownership of seeds. In southern France, farmers and cheese-makers concerned about the effects of U.S. trade sanctions have dumped truckloads of rotten fruit and manure at the doors of McDonalds' restaurants.

Ethical Issues

(i) What is Bioethics?

Ethics can usefully be defined as the branch of philosophy concerned with how we should decide what is morally wrong and what is morally right. Ethical conclusions need to be based on reason; consensus and take into account historically well established ethical principles and minority interests and be open to the possibility of change. Traditionally, ethics has concentrated mainly upon actions that take place between people at one point in time. In recent decades, however, moral philosophy has widened its scope by taking into account inter-specific and inter-generational issues. Ethics is the discipline concerned with what is good or bad, right or wrong. It has theoretical and practical aspects. *Bioethics* deals with the ethical implications of biological research, and the biological and medical applications of research. The ethical issues of biotechnology are up for debate in our culture now. Developments are outpacing the public's awareness and ability to determine correct courses of action. Ethical decisions can be taken at a number of levels from the individual to the international.

(ii) Law versus Ethics

'Ethics' and 'morality' are often used interchangeably, but they do have different aspects. For instance, practical ethics aims to guide right behaviour; 'morality' refers to the underlying moral values that are used to assess what is right and wrong. In the field of IP, some patent laws refer to inventions the exploitation of which would be contrary to ordre public or morality, and some trademark laws refer to trademarks that are contrary to morality. In this sense, 'morality' could refer to the shared values of a community, values that might differ from one

community to another. Law and ethics are closely interrelated, but they are not the same thing. Some acts that are legal might be considered unethical. As a simple example, it is normally unethical to tell a lie, but only in some circumstances is it a true crime. There can be strong commonality and consistency between the law of human rights, and ethical norms and expectations, but it would actually reduce the legal effect and status of human rights law to regard it as giving ethical guidance only. Sometimes legislators choose not to pass laws on certain issues, as a conscious choice to allow communities' ethical considerations to govern behaviour, instead of legal rules. Certain forms of stem cell research may not actually break the law of a particular country, but some might still argue that it is unethical.

Patenting within the biotechnological sphere and the subsequent opposition proceedings which have been undertaken by NGO's such as the Greenpeace, have become worried by prospects such as the patenting of life, have led courts to highlight the relationship between patents and morality. However it has to be kept in mind that the concept of morality is relative to the values prevailing in society. The decisions based on morality should not be based on what some members of the public find objectionable, but should include a detailed analysis of the effect on human health, economic impact, environmental issues and opinion of the population as a whole. The main point, however is that non-patentability would only mean that the invention is not the subject of any property rights, it can still be used and worked even if it is contrary to public interest and morality as it still lies in the public domain.

Some areas of law require the legal adjudicators to draw on morality in considering the decision making process. The patent law especially concerning the patenting of biotechnological inventions does just this. When the legislatures enact patent laws, the moral standards of the community to which they belong to are one of the factors which affect their content. Moreover, the patenting system cannot be considered to be an ethically neutral concept. A system can be considered to be ethically neutral when it does not affect A's interests vis-à-vis B's interest. The whole crux of patents is to exclude others from access to information contained in the claims and hence it cannot be considered to be morally or ethically neutral.

(iii) Human Rights Dimension

IP and bioethics have bearing on international human rights principles. The Universal Declaration of Human Rights and the International Covenant on Economic, Social and Cultural Rights provide for:

(i) The recognition of the dignity of the human being,
(ii) The right to the enjoyment of health,
(iii) The right to food,
(iv) The right to enjoy the benefits of scientific progress,
(v) The right to benefit from protection of the moral and material interests resulting from one's scientific productions.

The Sub-Commission on Human Rights has called for provisions "in accordance with international human rights obligations and principles that protect the social function of intellectual property". The Universal Declaration on Bioethics and Human Right also has relevance for how intellectual property rights in the life sciences are utilized.

(iv) What the International Rules say?

The WTO TRIPs Agreement permits, but does not require, national laws to exclude certain forms of inventions as patentable subject matter. Some of these possible exclusions have

bioethical aspects. Members of the WTO "may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect public order or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law" as well as "diagnostic, therapeutic and surgical methods for the treatment of humans or animals" and "plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes." Plant varieties must be protected "by patents or by an effective sui generis system or by any combination thereof."

The Grant of patent on higher life form such as human cells, gene, mice etc. has provoked a numerous ethical objections to the patenting of life. Most of them deal with the consequences that could arise subsequent to patenting of animals while the other arguments focus on the religious, philosophical and spiritual grounds. Many of them rooted in religion claiming that patent reduces Gods creature to mere material objects, degrades God given dignity of life forms by making it one's own property. However, there should be some sort of control on human being playing God using new technological development and acquiring patent in technological invention. This issue was addressed by the European Court in Relaxincase. Here, the claim was for patenting human gene encodes for Relaxin. It was held that patenting of a single human gene has nothing to do with patenting human life. Even if every gene in human genome were cloned it would be impossible to reconstitute a human being from the sum of its gene. And such patent do not confer any right over any individual human being. The tissue is taken with consent within the framework of gynaecological operations. Manylife saving substances were isolated in this way and thus serve social purpose, by contributing to humanity, life saving drugs and such inventions are industrially applicable technical solutions to a technical problem. Hence, they are patentable. Thus, using DNA technique gene was cloned making it possible subsequently, to produce synthetic Relaxin a hormone which relaxes the uterus during the child birth. Until it was isolated, gene coded for Relaxin was unknown hence; it was held that it is not mere discovery. It was in PGS, Green Peacethe patentability of transgenic plant was challenged on the ground of public Order and morality under the European Patent Law. The technical Board of Appeal provided definitions for the first time for "Ordre public" and "morality", and observed that they were to be applied individually as opposed to together. Ordre public was defined as "relating to protection of public security and environment" and morality was described as "relating to the belief in European society as some behaviour as right and acceptable where as other behaviours as wrong, this belief being founded on conventionally accepted standard inherent in European society and civilisation." And the board rejected the relevance of opinion polls and surveys presented by Green Peace.

The arguments which go against the patenting of animals are difficult to prove as many of them are factual assertions which are still to occur or to be proven. The DNA is considered to be intimately related to the species identity and hence no part of it should be controlled for commercial interest. In case of human beings, human DNA is unique and hence possesses intrinsic value of a sacred kind. It can also be put as 'Human DNA bears the image of God' and to tamper with them and own them for commercial and economic interests would hurt the sentiments of the many. The view that plants, animals and microorganisms comprising life on earth are part of the natural world into which we are born and hence the conversion of these species, their molecules, or parts into corporate property through patent monopolies is counter to the interest of the people of the country and world, has been taken by many. However most

of the religious and ethical issues arise out of product patents which have been given to organs, cells, genes and proteins. Hence one possibility that could be accepted by such religious leaders could be the issuance of 'process patents', whereby only the process involved in the manipulation of particular genes are patented rather than the genes in it.

Ethical and Related Issues in Biotechnology

(a) Organ Transplantation

As is widely known, the pig seems to be the most suitable animal for xenotransplantation of organs on humans. It is well on the cards that a genetically engineered pig would be soon available commercially in which the mechanism that leads to the hyper acute rejection of a pig organ when transplanted into human beings, would have been rendered ineffective. Transplantation of organs from such a pig on to a human being would then be no different from homotransplantations, for the success of which the protocols are already available and well established. When this becomes a reality, what about the Islamic world? Will they accept a pig organ, as for them pig is an unholy animal.

(b) Biological Weapons

It is most unfortunate that modern biotechnology has given a new face to the art and science of making and using biological weapons. Biological warfare is upon us. We can today design ethnic weapons that would affect only a particular segment of world's population. For example, Americans above 50 are known to have a depleted immune response. The depleted immune response in the older Americans could be a consequence of the fact that they have lived in a virtually semi-sterile environment so that their immune system has not been challenged enough and could have atrophied. On the other hand, we in India are being continuously challenged by low levels of infection in our environment and, therefore, our immune system is likely to be robust. The list of biological weapons on which considerable work has been done includes nearly 60 bacteria, viruses, other organisms, and toxins. (Examples would be: viruses that cause smallpox, Ebola fever, Marburg fever, Lassa fever, and various haemorrhagic fevers; bacteria that cause anthrax, plague, glanders and tularemia; and toxins such as botulin and ricin.) How ethical is it to manufacture and store them as is being done by many countries? Great Britain, the US, the erstwhile USSR (now Russia), Canada, Germany, South Africa, Japan, Iraq, Iran, Syria and North Korea are known to have had extensive biological weapons development programme. In 2003, the NIAID at the National Institutes of Health in the US, was to receive US $ 1.5 billion for developing means of combating agents causing small pox, tularemia, anthrax, plague, haemorrhagic fever (including Ebola, Marburg and Lassa fever viruses), and botulin toxin. Botulin is the most deadly poison known to us. We may need just half-a-kilogram of botulin to kill the entire population of the world, and the delivery of it would be easy, just put it in the water supplies as botulin is an intestinal toxin. Then, there are pests that can be released to destroy agriculture. There is, indeed, no doubt that biological weapons are the most dreaded ones today – far most dangerous than nuclear, chemical or conventional weapons.

(c) Bioinformatics

The day is not far off when, using DNA chips, it would be possible for a physician to tell a parent as to what the diseases are that a new-born child is likely to suffer from as it grows up. There is no problem for a physician if the disease is like sickle-cell anemia, or thallasemia, or cystic fibrosis as, in such cases, the child is bound to suffer from the disease. But what about the susceptibility genes where, according to current information, the doctor can only indicate

the chances that the child would have of suffering from the disease -let us say, type II diabetes? We still do not know what are the life-style or other factors that lead to the conversion of the susceptibility status to the disease status in the carriers of such genes. In the absence of this knowledge, let us assume that the physician tells the mother that there are 50 percent chances of her child suffering from diabetes after the child crosses 40. But it happens that the child doesn't suffer from the disease and leads a normal life all through. Could he, later, sue the doctor for keeping him and his family on tenterhooks that he may suffer from the disease? On the other hand, if the physician does not tell the parent about the presence of the gene in the child, and it turns out that the child does suffer from the disease when it grows up, the child and the parent can again sue the doctor saying that he withheld information which could have prepared them for the disease scenario.

Social and Ethical Concerns about GM Foods

Across the globe, food is a part of cultural identity and societal life, and has religious significance to people. Therefore, any technological modification resulting from the science of biotechnology, including changes to the genetic basis of crops or animals used for food may be met with social resistance. In many countries, people's interaction with nature, often correlated with religious perspectives, causes social and ethical resistance to modifications that interfere with genes. Whereas biotechnology does help achieve the avowed objective of food security and tide over food crises in many a country, the fact remains that still the reasons behind strong opposition and sentiments about GM foods are much more complex, unclear and variable in different regions of the world. While in developed countries and even advanced developing countries, surveys indicate that lack of information is not the primary reason for opposition to GM crops there. The public is not for or against GMOs per se-people discuss arguments both for and against GMOs, and are aware of contradictions within these arguments. Also, people do not demand zero risk. They are quite aware that their lives are full of risks that need to be balanced against each other and against the potential benefits. A key finding is that people do not react so much to genetic modification as a specific technology, but rather to the context in which GMOs are developed and the purported benefits they are to produce. However in less developed countries and developing countries, lack of knowledge and awareness plays a significant role in whipping up the passion and sentiments against the so called bogey of GM crops and its imaginary or otherwise ill effects for the society as a while. Irony is that most of the arguments raised against the GM crops are either shallow or far away from reality and hide the big picture. One major point of arguments against GM crops is their being unnatural and artificial. However the same argument was also raised at the time of introduction of pesticides and other weed eliminating elements for protection of crops. The opposition to GM crops and foods has as much to do with social and political values as with concerns about health and safety. Consumers' growing awareness of their rights and farmers' increasing fear of dependence on multinational companies are symptoms of a deeper concern about values and priorities, the type of environment people want, the role of biodiversity, tolerance of risk and the price that people are prepared to pay for regulation. Some people are concerned about the level of control exercised by a few chemical companies on seed markets. GMOs are emblematic of the powerful economic fears that globalization inspires. In certain regions, hostility to GMOs is symbolic of a broader opposition to the encroachment of market forces. These are perceived to be creating a world in which money rules with little consideration for historical traditions, cultural identities and social needs. The potential risk of out crossing and contamination by dispersed material from GM plants can pose problems for organic farming. Dispersal of

materials from GM crops (e.g-seeds) can occur over wide distances, depending on the plant characteristics and climatic conditions.

Environmental Issues

The term environmental ethic has been defined as relationship between man and his surroundings which establishes a cardinal sense of respect for land and not merely determines it as an exploitative resource. It also aspires to forge a more compatible existence of men and their fellow beings with the latter not only facing the brunt of an exploitation rage.

Biotechnology is also expected to have its impact on environment, such as safety from genetically modified living organisms, safety during transportation of such micro-organisms, form of recyclable material such as bio-plastics, bio-pesticides, recovery of waste lands and conservation of endangered species. While impacts of most biotechnology products are relatively predictable, GMOs do present risk to human health and environment and raised considerable uncertainties, in particular regarding their environmental impacts. Some of the concerns about the new technology include its potential adverse effects on biological diversity, and potential risks to human health. Here, the precautionary principle should be respected. When there are reasonable grounds for concern, even without complete scientific documentation, country should be reluctant to allow patentability, or even commercial use of GMOs until more knowledge is available. GMOs need proper control and an appropriate testing.

The possible health and environmental risks arising from genetically modified organisms are being addressed by Governments around the world. For example, the Cartagena Protocol on Biosafety to the Convention on Biological Diversity (CBD), which was opened for signature in May 2000, deals with these issues. The objective of the Protocol is:

> To contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focussing on trans-boundary movements.

The intellectual property standards established under TRIPs do not impede the right of a country to impose regulations or controls on the use of technology. In general, a technology that is deemed unsafe, hazardous to health or the environment can be banned or otherwise regulated, whether or not it is considered a patentable invention. Even so, TRIPs gives countries flexibility to deny patents to inventions, when using the invention would be contrary to human, animal or plant life, the environment or morality.

(i) Release of Genetically Manipulated Organisms (GMOs)

There are many examples in contemporary history where release of living organisms in an environment in which they were absent earlier, has led to enormous damage. For example, in India, Parthenium and Water hyacinth were unknown at the beginning of the 1950s. Since then, they have become major scourges. Both these plants have spread all over the country. Parthenium allergy is one of the most common allergies in India today, and Water hyacinth has choked innumerable lakes, riverbeds and water passages. Both have led to an enormous expenditure in remedying or controlling the situation arising out of their spread across the country. The origin of these plants is not absolutely clear, though it is believed that Parthenium came as a weed along with the Public Law- 480 supplies of wheat from the US to

India before the green revolution in India which made it self-sufficient in food grains. Unfortunately, no GMO released so far in the world – including India – has gone through such rigorous testing. The discovery in 1999 of the deadly effects of pollen from genetically engineered corn on immature monarch butterflies-with an almost fifty percent mortality rate for larvae that were exposed to the altered pollen-dramatized the environmental consequences of genetic engineering in an easily comprehensible fashion. Effects on other beneficial insects, the threat of "super weeds," genetic contamination from engineered trees and fish, and the surprising death of soil microbes exposed to an experimental genetically engineered bacterium in an Oregon laboratory have all contributed to raising the level of environmental concern. Ultimately, no one can predict the full effects of releasing countless millions of new, reproducing, genetically manipulated organisms on the earth's diverse natural ecosystems.

(ii) Tissue Culture

One would normally think of tissue culture as one of the safest and most innocuous biotechnologies, which is neither polluting nor likely to pose any ethical or related problems, but look at this possible scenario. In Malagasay, some 75,000 farmers are employed in cultivation of vanilla. It is perfectly possible that in the years to come, vanilla that is marketed would come from plant parts grown in tissue culture. What would then happen to the 75,000 farmers employed in vanilla cultivation in Malagasay? An appropriate solution would be that the Government of Malagasay should be the first to develop this technology and train the farmers in its use, including value addition. But the problem is: how many Governments, especially of the developing countries, do look into the future in this manner? This is a world-wide challenge: to look into the future of biotechnology and prepare ourselves to use it for maximizing gain to mankind in an ethical framework.

One useful way to simplify the range of issues arising in connection with environmental impact is to note that answers to this question can raise three different kinds of ethical concerns. *First* are human health effects accruing from environmental exposure, such as air or water borne pathogens (as opposed to ingestion through food).*Second* are catastrophic impacts that would disrupt ecosystem processes in ways that threaten to destabilize human society. This includes dwindling energy supplies, human population growth and global warming. Finally there are effects that are felt less by humans than by the broader environment. These may be classified as eco-centric impacts. Environmental impacts in the first category manifest themselves as human injury or disease. They include cancer induced by chemical pollution, emphysema and lung diseases from air pollution, poisonings and non-fatal diseases such as allergies and reduced fertility speculatively associated with hormone disrupting chemicals in the environment. Although the scientific and legal issues that arise in establishing the connection between cause and effect are tortuous, the ethical imperative to limit these risks is very clear. Ethical and quasi-ethical issues arise because it is not clear how to resolve uncertainties that arise in assigning a probability to the unwanted impact, and because there are different ways to think about the social acceptability of environmental exposure to human health risks. Although it is certainly possible that food and agricultural biotechnology could pose such risks, products currently under development for use as food have not been linked to any known human diseases that would be contracted by environmental exposure.

Agricultural technologies are potential polluters, contributing to human health risks, and agricultural land use competes with wilderness preservation. Prior to 1999, crop biotechnology was not widely associated with environmental impacts on wilderness or endangered species. In that year news reports that Bt-crops could affect monarch butterflies enlivened the prospect of

unintended impact on nontarget species for the first time. This has awakened public recognition of the way that agricultural biotechnology could have an impact on wild species, and provides an example of how eco-centric environmental impacts could be brought about by genetic agricultural technologies. In Canada, genetically engineered canola could outcross with wild rape. Research on genetically engineered fish has long been associated with the potential for negative impact on wild populations. There are also less well known products, such as recombinant vaccines, that could also have negative impact on wild habitat. As experience and experimental studies accumulate, the list of possible hazards is expanding, and scientists' ability to quantify the likelihood that such hazards will materialize is increasing.

Conclusion

It is a social responsibility to use of biotechnology to save or improve lives, improve the quality and abundance of food, and protect the environment. As our companies develop technologies that promise to benefit humankind, these technologies also may bring ethical questions. Biotechnology has extraordinary potential to improve the health and well-being of people in the developing world, but significant impediments exist to the development and dissemination of diagnostics, therapeutics and vaccines for the infectious diseases prevalent in developing countries. While biotechnology can greatly improve the quality of life, it is well recognized that this new technology should be approached with an appropriate mixture of enthusiasm, caution and humility. IPRs for biotechnological inventions, pose complex problems relating to access to technologies, unfair exploitation of genetic resources and fair and equitable sharing of the financial benefits. Although steps are necessary to preserve existing biodiversity and enhance equity in international obligations, financial benefits from genetic access legislation may often be exaggerated. Certainly, it would be paradoxical if these countries forgo the potential benefits of biotechnology to solve some of their most pressing problems of poverty, disease and malnutrition on account of these exaggerated fears or hopes.

To conclude with the issues it would be pertinent to say that as far as patent law is concerned, a modified organism is certainly good subject matter for patent if it fulfils the requirements. Ethical issues are not however connected with patent law. Exclusion is to patenting on ethical or moral grounds or grounds of public policy. Thus unlike economic arguments against patents on life forms, ethics does not have a place in disputes over patent policy. The latter though they might be legitimate in principle, are not a matter of law. It is put forward that ethics has never been and cannot be a break to scientific research. To reiterate, exclusion from patentability cannot be justified mainly because technology is dangerous or regulation of dangerous material is the solution. This has been said so in the report of FAO Panel of Experts on Food and Agriculture. As long as an invention does not have a solely destructive use, morality or ethics is not a rational bar to its use. However, for now, patent laws should be amended so as to exclude humans from patentability. With regard to environmental safety issues, it is less to do with patentability and more about stringent regulatory and approval mechanisms for the commercial use of such organism that is needed. Given the existing technological gap between developed and developing countries and the capital-intensive nature of product development, the best way forward for developing countries seems to be collaboration and not confrontation. Multilateral developmental institutions should also be encouraged to help developing countries make the transition to higher level of capabilities in biotechnology through both financial and technical assistance for R&D projects, including obtaining and defending IPRs at home and abroad.

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