AN ANALYTICAL STUDY OF MORAL AND ETHICAL ISSUES RELATED TO PATENT IN BIOTECHNOLOGICAL INVENTIONS

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In the era of 21st century, biotechnology is transforming our lives in ways we never imagined possible. It continues to captivate the average person by providing a solution to many odds that were previously thought to be irreversible. Biotechnology is a synergistic combination of natural sciences and technology-driven industrial art in which biological processes are used to exploit and manipulate living creatures or biological systems in the process of developing or producing a product or providing a technological solution to the real world. In 1919, Karl Erkay, a Hungarian engineer, created the term “biotechnology”.

Biotechnology's dynamic nature makes a comprehensive definition impractical. However, authors, experts, and organizations have attempted to characterize it nearly perfectly.

The US Office of Technology Assessment is credited with developing an extensive official definition for the first time, stating that *"biotechnology includes any technique that uses living organisms (or parts of organisms) to make or modify products, improve plants or animals, or develop microorganisms for specific use."*[1]

Recombinant DNA technology, or rDNA, offers the chance to learn new scientific things and has the potential to do amazing things that will make life better. However, if we can modify the sequence of genes to create a protein that stops a human illness, we can utilize that knowledge to create a protein that is lethal and contagious. If humans can genetically modify plants to produce more fruit, we could unintentionally or intentionally alter the genetic makeup of the material to make it less accommodating to the environment. Is it feasible to introduce a specially designed life form that can unintentionally disrupt natural cycles and have

[1] Philip W Grubb, Patents for Chemicals, Pharmaceuticals and Biotechnology: Fundamentals of Global law, Practice and Strategy 245-246 (Oxford University Press, 4th ed., 2006).

unanticipated implications that are beyond our comprehension, even if we can manufacture algae that can produce energy?

What is Morality?

Morality refers to the opinion that some action is right and acceptable while others are wrong. Judging right and evil must be based on recognized ideals that are firmly embedded in the culture of the community and civilization. While scientists can identify the positive aspects of biotechnology, and they are no more competent than anybody else to address the ethical and moral difficulties that may develop as a result of employing its products. Only the general people, through a properly structured legal system can ultimately determine the relative importance of the benefits, threats, and impacts.

Article 6(2) of Directive[2] provides guidance on the definition of '*ordre public'*, or morals, even if the EPC (European Patent Convention) language is quiet on the subject and it read as:

"On the basis of the paragraph I[3], the following, in *particular*[4], shall be considered unpatentable:

a. processes for cloning human beings;
b. processes for modifying the germ line genetic identity of human beings;
c. uses of human embryos for industrial or commercial purposes;
d. processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes."

In the case of *Lubrizol Genetic Inc.*[5], on the grounds that it was intrinsically unethical and endangered the environment, the opponent challenged the patent that had been issued for a hybrid transgenic plant that made the plants immune to the pesticide. The EPO (European Patent Office) reviewed the objection in light of the guidelines for patent examination, which stated that "a fair test to apply is to consider whether it is probable that the public in general would regard the invention as so abhorrent that the grant of a patent right would be

[2] EU Directive on the Legal Protection of Biotechnological Inventions, 1998.

[3] That is, *ordre public or* morality.

[4] The phrase 'in particular' suggests that the list of unpatentable subject-matter is illustrative rather than exhaustive.

[5] T0320/87 (1990).

inconceivable" in order to determine whether an invention is contrary to the ordre public or morality. By applying the "public abhorrence test", the EPO (European Patent Office) disregarded every objection.

In this instance, the EPO determined that the exemption from patentability specified in Article 53(a) EPC only addressed severe situations that were unanimously viewed as repugnant.

The EPO used the *"public abhorrence test"* in the *Hormone Relaxin case*[6] as well, which involved the granting of a DNA fragment encoding a human protein generated by pregnant women with beneficial medical applications.

Here, the EPO noted that if the invention involved the patenting of human life, the mistreatment of expectant mothers, or a reverting to tyranny and the component sale of women, it would be repugnant to the vast majority of the public.[7]

In US Patent Law also, moral standards were frequently upheld in court by virtue of Section 101 utility requirement—which stipulates that a process, machine, manufacturing, composition of matter, or improvement thereto be "useful"—US patent law does not, in and of itself, have a morality clause.

Justice Story stated in *Lowell v. Lewis*[8]: "The invention must not be frivolous or detrimental to the welfare, sound policy, or morals of society. That is all that the law requires." Therefore, the word "useful" is included in the Act to contrast with "mischievous" or "immoral."

Judge Bryson of the CAFC later in the cases of *Juicy Whip Inc. v. Orange Bang Inc. and Unique Beverage Dispensers Inc.*[9] noted, however, that the requirement of utility is not a directive to the PTO or the courts to act as arbiters of deceptive trade practices where other agencies of the State have been assigned this task. This implied that inventions used to deceive buyers, whether or not morally wrong, can no longer be considered excluded from patentability on such grounds.

[6] O.J.E.P.O. 388 (1995).

[7] *Oliver Mills, Biotechnological Inventions: Moral Restraints and Patent Law 56 (Routledge, New York USA, 2016).*

[8] 15F Cas 1018 (no.8568), Circuit Court, Massachusetts 1817.

[9] 18F 3D 1364 (1999)

Judge Bryson added, *"It has not been used widely in recent years that innovations are invalid if their primary goal is to serve immoral or criminal purposes. For instance, it is no longer legal for courts to reject gambling equipment patents on the grounds that they are immoral."*[10]

Morality and Issues under Indian Patent Law

India acknowledges the exclusion of public order and morality from patentability, just like Europe does. Section 3(b) of the Patents Act, 1970, which prohibits the primary or intended use of an invention for commercial exploitation in the event that it could violate public order, morality, or seriously harm human, animal, or plant life, health, or the environment, contains a morality clause pertaining to Indian patent law. This is also stated in the Manual of Patent Practice and Procedure, 2005 that- more precisely, any biological material and method of producing it that could seriously harm human, animal, or plant life or health, or the environment, including the use of those that would be against public order and morality, are not patentable. Examples of such materials and processes include terminator gene technology.[11]

A few instances of non-patentable biotechnology products that violate public order and morals are given in the Guidelines for Examination of Biotechnology Applications for Patent, published by the Office of the Controller General of Patents, Designs, and Trademarks in March 2013:

The following practices are prohibited:

(a) cloning humans or other animals;

(b) altering a human's germ line;

(c) changing an animal's genetic makeup in a way that will likely cause suffering for it without providing significant medical or other benefits to humans or other animals;

(d) creating seeds or other genetic materials that contain components that could have a negative impact on the environment; and

(e) using human embryos for commercial purposes.

Gene-related inventions must pass a litmus test to meet India's deeply ingrained moral, cultural, and religious values in order to be eligible for patent protection. Therefore, in India, the

[10] Supra note 7 at 47-48

[11] Manual of Patent Practice and Procedure (2005), Annexure I, Page 142, Para 7.0.

patentability of ideas based on genes is heavily influenced by public morals and order. A similar concern is expressed in the Indian Patent Manual of 2011 when it states, *"An invention, the primary or intended use of which is likely to violate the well accepted and settled social, cultural, legal norms of morality, e.g. a method for cloning of humans."*[12]

Morality and Animal Suffering

Animals suffer and suffer for purposes that seem trivial, hence using testing on animals for genetic engineering purposes is sometimes used as a moral justification against biotechnology. Such an argument is hard to support since it is founded on an absolutist perspective that upholds only one value—animal protection—while moral decision-making necessitates the ongoing consideration of competing values.

Particularly, according to Article 6(2)(d) of the Directive[13], *"processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes"*[14] are listed as being unpatentable due to *ordre public* or morality. It is interesting to observe that the provision makes no mention of flora. This implies that it is acceptable to modify plants genetically, and this will probably be decided based on standard patentability standards. This suggests that inventions pertaining to animals are subject to a higher moral standard than inventions pertaining to plants.

An animal in the Harvard Oncomouse was filed for patent for the first time in European history. The method for creating a transgenic non-human mammal[15] with oncogenes and a transgenic mammal that is cancer-susceptible was claimed by the inventor. According to the EPO Technical Board of Appeal, the innovation in question does not violate public decency or order.[16]

[12] Manual of Patent Practice and Procedure (2011), Chapter 08.03.05.02.f, Page 82.

[13] EU Directive on the Legal Protection of Biotechnological Inventions, 1998.

[14] Article 6(2) of the EU Directive on the Legal Protection of Biotechnological Inventions, 1998.

[15] A mammal is a living being that breastfeeds its offsprings. As such, human being is also a mammal.

[16] EPC under Article 53(a) prohibits patent protection for invention the exploitation of which is contrary to public order and morality.

The board believed that the patent may be denied on the basis of "public order" and "morality" if the invention's risks outweighed its rewards. When new technologies engage higher living forms, it is important to take into account both the risk and the potential for harm to these life forms. Different interests needed to be balanced in the current situation. On the one hand, humankind's fundamental interest in finding a cure for common and dangerous diseases was present; on the contrary, the ecosystem needed to be safeguarded against the unchecked spread of undesirable genes, and animal cruelty needed to be curbed. Patents would be denied for reasons of public order and morality if the invention resulted in any type of ecological imbalance or animal suffering.

Ethical Issues and Human Being

All processes that either directly or indirectly involve human embryos are debatable because they rest on assumptions about things like the origin of life and whether or not human life should be protected to the fullest extent possible at each stage of development. Those who reject research on human embryos cannot, then, entertain any patenting regarding this subject because the issue of the embryo's moral standing and dignity is still very contentious. The possibility of successfully producing human clones has opened up a wide range of options, sparking discussion about whether the procedure will ultimately result in the "commercialization" of humans since the ability to create life may be "marketed" and people may become "disposable and recyclable products."

As a matter of fact, the policy responses have been shaped by the issue around human reproductive cloning. In addition to recognizing *"the importance of therapeutic cloning as providing possibilities for preventing and fighting diseases"*[17], an attempt was made to create a distinction between therapeutic and reproductive cloning. Reproduction of embryos by embryo splitting is rejected by the draft WHO Guidelines on Bioethics as "morally unacceptable" and "contrary to human dignity," but non-reproductive cloning research with the clinical goal of repairing damaged tissue has significant potential benefits and ought to be supported. Despite these opinions, the United Nations General Assembly resolved in 2005, a resolution known as the UN Declaration on Human Cloning, to forbid all kinds of cloning, stating them as incompatible with human dignity and the preservation of human life.

[17] N.S. Sreenivasulu, *Biotechnology and Patent Law: Patenting Living Beings* 207 (Manupatra Publications, Noida, 2008).

The US judiciary holds that the cloning of humans and their patenting are flagrant violations of human rights, and that they are completely unconstitutional under both the US Constitution and patent law since a thirteenth amendment to the US Constitution forbids the enslavement of human beings. This position was made clear in *the Pioneer Hibred International case*[18], where it was decided that the prohibition against human cloning stems from its violation of both public policy and human dignity. However, because procedures or techniques for human cloning were considered patentable, the regulation in this area caused some questions. At this point, it seemed that the human rights arguments strongly advocated for the complete outlawing of human cloning. At this point, it seemed that the issue of human rights arguments strongly advocated for the complete outlawing of human cloning. The United States introduced laws in 2003 that outlawed human cloning and stipulated a 10-year prison sentence for anyone who executes, attempts, facilitates, aids, or assists in the cloning of human beings.[19]

Like a number of other countries, India opposes reproductive cloning, believing it to be wrong and a violation of human values and dignity. However, it is in favor of stem cell research, arguing that the new technology may be used to treat specific illnesses.[20]

Patent of Human Genes: Moral and Ethical Concern

Many people believe that genetic engineering is inherently not acceptable for the reasons below as :

1. It is an attempt at the “creation of God”.

2. Without technological assistance from humans, genes should be passed down from generation to generation as a symbol of humanity's shared heritage.

3. Genes should not be interfered with because they are found naturally in organisms.

Basically, the point of view is that, even if the overall benefits of biotechnology outweigh the risks, humans simply should not undertake it, regardless of how skilled they are at it. Simply

[18] *Pioneer Hibred International* v. *Holden Foundation Seeds Inc.*, 35F, 3d. 1226.3, USPQ, 2d. 1385 (8th Cir. 1994).

[19] Human Cloning Prohibition Act, 2003

[20] Human rights and ethical considerations surrounding stem cell research in India are addressed by the Government of India's DNA Safety Guidelines and the ICMR's guidelines. The scientific, technological, moral, legal, and human rights aspects of embryonic stem cell research would be examined by the National Apex Committee for Stem Cell Research and Therapy (NAC-SCRT) and an Institutional Committee for Stem Cell Research and Therapy (IC-SCRT), both of which are registered under NAC-SCRT.

said, interfering with nature's process is tantamount to "playing God". Accordingly, there is no compelling moral argument against genetic engineering only because it gives humans dominion over living things. Furthermore, it does not appear that the dangerous nature of genetic engineering, the results of which are yet mostly unknown, constitutes a compelling moral case against biotechnology. Genetic engineering is not the only field to raise safety issues. Because safety concerns are unique, each needs to be evaluated within its own context.

It is generally noted that patenting human genetic material, including genes, DNA, and cells, is equivalent to claiming ownership of the human body or life as a private asset. Owning people or their lives would be the same as slavery, which is egregiously against human rights and against human dignity. The attribution of human dignity as a foundation for human rights reflects a diversity of intellectual, moral, and theological traditions and cultures. The ethical foundation and meaning of human dignity are flexible and ambiguous.

Human rights and principles are being violated here on two separate levels. Two types of violations occur when living things and human bodies are changed, and the second form involves obtaining patents for the altered bodies. Genetic engineering allows for the manipulation of the human body by the removal or isolation of genetic material, such as genes and DNA, or the introduction of foreign genetic material into the body. Intellectual property rights pertaining to human genetic material eventually spark contentious discussions about the morality of possessing human genetic material and the ethics of altering human anatomy.

For both specialized newcomers and existing companies, biotechnology has emerged as a novel and difficult approach. Genetic manipulation of biological resources can be applied at any level, from the genus or species to the particular crop variety, to shape them into the desired form. No matter how much support legislators may give manufacturers, engineering biological resources may jeopardize environmental manipulation and continue to be a source of public unease. Although increased output might benefit developing nations greatly, there is more risk than benefit associated with cloning-like technologies that open the door to organ development through stem cell and embryo research. Due to the rapid advancement of technology over the past ten years, a new field known as bioinformatics has emerged. This field deals with genomic data and uses large computers and our understanding of the biological processes or functions of individual genes to map genes (as done in the Human Genome Project, which is now extended to animals as well).

To provide more contribution in the development of patenting, it is necessary to focus over this area of patenting. Although, many efforts have been made in patenting the human genes as well as of animals and it has been a concern of debate globally. But still there must be a way to work on patenting the biotechnology.

Conclusion and Suggestions

It is factual that biotechnology has been around for a long time. Fermentation technology was once utilized proactively to create and preserve items for an extended period of time. These days, genetic engineering can be used to modify living things and make them behave and function differently from how they would in the wild. Biotechnology, which gives credit to genetic engineering, is sometimes referred to as the technology of the present. Because biotechnological inventions differ significantly from chemical and mechanical motion inventions, which have traditionally been the subject of patents, modern biotechnological advances, particularly genetic inventions, have posed new and noteworthy issues1 before the national patent laws that are currently in place throughout the world.

The gene has gained popularity after the advent of human genomics and the successful completion of the well-known Human Genome Project (HGP), which may be more due to the informative value of the gene than to its physical attributes. A patent is a topic of jurisdiction. Since patents are inherently territorial, different countries may decide to grant patent protection to varying degrees.

India acknowledges the exclusion of morality and public order from patentability. The Indian Patent Act, 1970 makes it clear that the country sympathically prohibits patents for genetics and gene-based technologies that violate public morals or order. "An invention, the primary or intended use of which is likely to violate the well accepted and settled social, cultural, legal norms of morality, e.g. a method for cloning humans," according to the Indian Patent Manual, 2011, expresses the same worry. According to this study, patients suffer when diagnostic genes are patented since they are unable to obtain second opinions and verification testing. Licensing procedures are more significant in the context of diagnostics gene patents than the patent itself. For the advancement of social benefit is the penultimate objective of patents.

Some **suggestions** can also be summed up as follows:

(i) Some steps may be taken to patent the microorganisms and microbiological processes.

(ii) Also there must be a review of the Article 27.3 (b) of the TRIPs Agreement in context to the patent of microorganisms and microbiological processes.

(iii) In addition to the suggestions, it can also be added that every biotechnology company "pool" its intellectual property rights, which could be further enabled by a cross-licensing program. This would give scientists a greater opportunity to gain access to a wide range of patented genetic materials.

(iv) It is recommended that the patent offices establish an exclusive specialized committee to expedite and support the review of patent applications pertaining to biotechnological inventions.

(v) It is recommended that product patent protection be used sparingly. Furthermore, because they describe a natural phenomenon, method patents that demonstrate the connection between a disorder or disease and its related gene shouldn't be eligible for patent protection.

(vi) To expedite the examination of patent applications for biotechnological inventions, an expert committee should be established in patent offices to address the complexities of the field.

(vii) Tax benefit is now offered for costs related to filing patents in India, but not for those submitted outside of the country. Under Section 35 (2AB) of the Income Tax Act, it is proposed that expenses related to filing patents outside of India be given a weighted deduction, as the development of intellectual property rights in products exported to controlled markets is a prerequisite.

(viii) It is recommended that product patent protection be used sparingly. Furthermore, since they describe a natural phenomenon, method patents that demonstrate the connection between a specific illness and its related gene should not be eligible for patent protection.