HUMAN GENETIC RESEARCH AND PATENTING: AN OVERVIEW

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Abstract

Turbulence and uncertainty regarding the patenting of human genes and its research has been raised time and again, giving rise to formidable questions pertaining to the bonafide intentions associated with the same, human beings are still trapped within the realm of basic experimenting and learning regarding the genetic material that are inherent within us and this has paved way towards many conflicts. Though unrelenting efforts are been put forward by research scholars and scientists all over the globe, focussing on the medical and scientific aspects of human genetic patenting, it has been appalled by an array of problems like research stagnation, commercial interests of business tycoons, disparity in the patent laws of different countries, issues relating to sense of property, balance between patent right on one hand and ethics, order and morality on the other etc. Though we can hope for the best to happen, what lies ahead is unknown as it would be impossible to brush aside the hysteria of problems that would arise if we try to exploit the remedy for all human anomalies. The patenting of human genes is a miracle in itself that would reform the medical world, as it would enhance the scope and approach towards gene therapy. The need of the hour is to enable a strong non-discriminatory collaborative culture where knowledge and innovative technologies would be shared between nations and framing of a universality of rules by enacting a common legal framework that would be equitably followed by all nations so that the myriad of problems that might arise in the future can be nipped off at the budding stage itself as transforming the problematic gene would be the ultimate therapy that human beings would ever need to improve their quality of life.

Keywords: Human Genes, Genetic Patenting, Research Stagnation, Commercial Interest, Patent Laws, Sense of Property, Morality, Ethics and Order, Knowledge, Innovative Technology, Universality of Rules, Legal Framework, Gene Therapy

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Introduction

Science has always sought to unravel the mysteries of our physical world with the sole objective of betterment of the human condition. The scientist seeks the truth, as a corollary destroys ignorance, and finds solution to specific human conundrum. The problem arises as the scientist may err, the truth sought maybe unsavoury, awareness unwelcome and solution simply may lead to more problems along the way.

Every scientific innovation that has heralded great strides in human development has faced harsh resistance. The same admixture of great expectation and equally great mistrust leading to resistance is being faced at present by the relatively new field of genetic research and study.

To begin there were always protest and ethical issues regarding genetic manipulation of living organism and the issue has only escalated to newer dimensions with implications related to patenting. Human genetic patenting is the epitome of the conflict mentioned above. It can be crudely said that the only thing that was left to be patented for the benefit of humans was the human.

Patent

The word patent originated from the Latin term *'literae patentes'* meaning Letters Patent, meaning 'open letters'.[1] The Letters Patent were the sovereign grant of a patent that strictly commanded all subjects not to make use of or put in practice the said invention, the breach of which would result in sanctions not only as penalties to the sovereign but also damages claimed by the patentee.[2] As per Halsbury's Law of England, the word patent is used for denoting a monopoly right in respect of an invention.[3] Thus patent is a monopoly right conferred by the Patent Office on an inventor to exploit his invention subject to the provisions of the Patent Act for a limited period of time wherein the inventor is entitled to exclude anyone else from commercially exploiting the invention. In *Telemecanique and Controls(I)Limited v. Schneider Electric Industries*[4] the Division Bench of the Delhi High Court observed that patent created a statutory monopoly protecting the patentee against any unlicensed user of the patented device i.e "A monopoly of the patent is the reward of the inventor "

The Patent rules of each country might vary as the patent might only be valid within that

[1] Halsbury's Laws of England, vol 35, fourth edn, p132,para 303, fn 1.
[2] *General Tyre and Rubber Company v. Firestone Tyre and Rubber Company Limited* (1974) FSR 122.
[3] *Bajaj Auto Ltd. v.TVS Motor Company Ltd*.,2008 (36)PTC 417 (Mad.)at p.439.
[4] SA,2002(24) PTC 632(Del)(DB).

country and it is essential for commercialisation of the product.

Genetic material

Every individual is unique and quintessentially human because of his or her genetic makeup. Genes are not just fixed entities but they play a complex role in shaping our identities and is the controller of our lives as we inherit them, pass them to our children and further down the line. It is the genetic material which acts as a guiding source for the transmission of information from one generation of organisms to the next.

A genome is the entire DNA contained within the cell of a living being. Each molecule of human DNA has billions of nucleotides arranged as if steps on a ladder and this sequence of nucleotides determine the traits of an organism. Genes, as a natural consequence of their nucleotide sequences, build proteins, and proteins build bodies. Genetic material is passed among large organisms by vertical transmission from parent to offspring. Each offspring resembles its parent more closely than it resembles a randomly chosen member of its species because the exact sequence of genetic instructions on how to build the body have been inherited from the parent. Small errors in copying genes are known as mutations, and their proliferation throughout a gene pool drives the process of evolution.[5]

This is the scientific aspect of procreation and genetic transference but in a philosophical or metaphysical perspective when viewing people not as humans but as individuals and genetic material, the very essence or proprietary right of each individual, science comes in direct contract and conflict with ethics, religion and morality.

Gene patenting

A gene patent is the exclusive rights to a specific sequence of DNA (a gene) given by a government to the individual, organization, or corporation who claims to have first identified the gene and once a gene patent is been granted, the holder of the patent dictates how the gene can be used, in both commercial settings, such as clinical genetic testing, and in non commercial settings, including research, for 20 years from the date of the patent and thus gene patents have often resulted in companies having sole ownership of genetic testing for patented genes.[6]

[5] Genetic Science, Retrieved from https://science.howstuffworks.com/life/genetic.

[6] Can genes be patented ,U.S National Library of Medicine, Retrieved from https://ghr.nlm.nih.gov/primer/testing/genepatents.

Examples of gene patenting

1. **DE-B- 102004386**

Patent holder: Chen Y. et al.; U.S. Patent No. 7,482,157.

Date of granting patent: June 2010.

Patent granted for having as its object the provision of genes related to the production of monacolin K[7] from the mold Monascus. The claims cover an isolated DNA molecule comprising a polynucleotide relating to mkA and encoding a polypeptide having an activity selected from β-ketoacyl synthase, acetyltransferase, dehydratase, methyltransferase, and ketoreductase.

2. **DE-B- 10149715**

Patent holder: Schwab H. et al

Date of granting patent: April 18, 2013

This patent was granted for covering short sequences, polynucleotides from the bacterium Rhodococcus ruber and encoding an esterase.

3. **DE-B- 19983297**

Patent holder: Flament D. et al; U.S. Patent No. 6,511,838.

Date of granting patent: July 4, 2013.

This patent covered the naturally occurring gene sequences from a marine bacterium coding for a β-agarase.

4. **EP-B- 1668029**

Patent holder: International Livestock Research Institute, Kenya.

Date of granting patent: December 25, 2013.

This patent was granted for useful sequences like probes for tick-borne diseases in cattle and other animals and for the production of vaccines.

5. **EP-B- 2021362**

Patent holder: Innoventus

Date of granting patent: January 8, 2014..

The patent was granted for an isolated and purified structural gene encoding a fluorescent protein.

6. **EP-B- 2311468**[8]

Patent holder: Perseus Proteomics

Date of granting patent: January 15, 2014.

[7]Monacolin K is a naturally occurring statin which is commonly known as lovastatin.

[8] Gene overexpressed in cancer, Europe PMC, Retrieved from http://europepmc.org/patents/PAT/EP2311468.

The patent was obtained for a gene and protein of the gene that was useful in the treatment of bone cancer.

7. EP-B- 2129781

Patent holder: Novozymes

Date of granting patent: January 22, 2014.

The patent was granted for an isolated polypeptide having phytase activity and an isolated nucleotide sequence that encodes it.

8. EP-B- 2155219[9]

Patent holder: United States of America

Date of granting patent: February 19, 2014.

The invention relates to an aluminium tolerance gene and the patent was granted for an isolated or recombinant DNA molecule encoding a polypeptide of listed amino acid sequence that is responsible for the Alt SB locus for aluminium tolerance in Sorghum bicolor.

9. EP-B- 2028278

Patent holder: Whitehead Institute for Biomedical Research

Date of granting patent: March 19, 2014.

The institute obtained a patent for isolated double-stranded RNA from 21 to 23 nucleotides in length in the form of two separate RNA strands, perfectly complementary to an mRNA and mediating RNA interference by directing cleavage of the mRNA to which it is perfectly complementary.[10]

Human Genome Project

In 1934, James Watson and Francis Crick described the double helix structure of deoxyribonucleic acid (DNA), the chemical compound that contains the genetic instructions for building, running and maintaining living organisms. Moreover, by the mid 1970's, different methods were developed to determine the order and sequence, of the chemical letters in DNA and in 1990, the National Institutes of Health (NIH) and the Department of Energy joined with international partners in a quest to sequence all 3 billion letters, or base pairs, in the human genome, which is the complete set of DNA in the human body.

On April 2000, the International consortium of the project announced that 2 billion of the 3 billion "letters" that constitute the genetic instruction book of humans have been deciphered and deposited into GenBank, the

[9] The sorghum aluminum tolerance gene, sbmate, Retrieved from https://patents.google.com/patent/EP2155219B1/en.

[10] Patentability of Genes: A European Union Perspective, Paul Cole, PMID: 25324232.

public database of DNA sequence operated by the National Institutes of Health and was made accessible freely to all scientists in industry and academia without any restrictions.[11] In April 2003, researchers successfully completed the Human Genome Project, under budget and more than two years ahead of schedule.[12]

The Human Genome Project was a memorable milestone for the rapid advance of science and technology as the project helped in disseminating information and bringing about transformations that brought about enormous and yet to be fully comprehended changes in the scope and approach towards human genes. This international collaborative research program gave the world a resource of detailed information about the structure, organization and function of the complete set of human genes. It also gained a lot of public attention and spurred a revolution in biotechnological innovation, as the data generated by the project were freely made available on the internet, thereby accelerating the pace of medical discovery around the globe. The ultimate goal of the project was the complete mapping and understanding of all the genes of human beings[13] and the social, ethical and legal implications of the project provided researchers with powerful tools to understand the genetic factors in human disease, paving the way for new strategies for their diagnosis, treatment and prevention. Though the complete sequence of the human genome could be deciphered, there was a great roadblock ahead as to understand the functioning of the complex parts that work together in human health and disease.

Gene Therapy

Though the initiatives and clinical trials for gene therapy had started even before the completion of the Human Genome Project, once the Project turned out to be a successful venture, the possibilities associated with gene therapy became limitless and thereby a futuristic dream for millions of scientists all around the globe, turned into a reality as it would be the ultimate therapy that human beings would ever need and therefore, it can be said to be the greatest revolution of science which came as a thundershower and retransformed the medical world as scientists and researchers could nip the cause at the budding stage by transforming the problematic gene instead of spending years to find drugs and medicines for a particular disease.

[11]The Human Genome Project, Retreived from http://www.ls.huji.ac.il/michall/papers/HumanGenome.pdf.

[12]Fact Sheet of the Human Genome Project,National Institutes of Health,Retrievd from https://report.nih.gov/NIHfactsheets/Pdfs/HumanGenomeProject(NHGRI).pdf.

[13] National Human Genome Research Institute ,Retrieved from https://www..genome.gov.

Gene therapy can be defined as the introduction of nucleic acids into cells for the purpose of altering the course of a medical condition or disease. By introducing new cells into the existing cells, the defective or mutated gene can be transformed into a normal gene and thereby someone born with a particular disease can be cured of the same as gene therapy has turned out to be a miracle that will save individuals from disorders and diseases that they have been suffering from.

Several inherited immune deficiencies like Severe Combined Immune Deficiency (SCID), Adenosine Deaminase Deficiency (ADA),Blood Diseases, Haemophilia, Cancer, Fat Metabolism Disorders ,Parkinson's Disease, Hereditary Blindness, Heart Failure, Acute Lymphoblastic Leukemia, Bone cancers etc. has been successfully reduced as a result of gene therapy through clinical trials.

Though gene therapy has provided many people with a chance to lead a normal life, the genetic tests , genetic screening and research involved to isolate the particular gene associated with it , increased risk of abortions once prenatal tests for babies with genetic disease is done, high cost involved in gene therapy and the chances of it been monopolised by the cosmetic industry for anti aging techniques are greater.

However, its advantages outweigh its disadvantages, as over the years many successful clinical trials have been initiated in gene therapy and the initial thought has been transformed into a reality[14] that is going to change the future of human race, as gene therapy is the future of the medical world.

Problems associated with the patenting of Human Genes

1. **Sense of property**

Human ownership has been relatively simple in the olden days; they included land, cattle and resources thereupon. Law of the land has been perfected for protection and conflict resolution in terms of the traditional property. The advent of the concept of intellectual property and its subsequent flourishing in the global stage had created a vast legal lacunae. Efforts have been underway to fill the same and it has been successful in varying degrees in different nations all over the world. The problem lies, however, in the lack of uniformity and universality in these laws. There is more or less a structured confusion in the realm of intellectual property and conflicts arise normally. The confusion is heightened in case of human gene patents as the

[14] Gene therapy, Mark A. Kay, Dexi Liu, and Peter M. Hoogerbrugge,Proc. Natl. Acad. Sci. USA Vol. 94, pp. 12744–12746, November 1997,Retrieved from http://www.pnas.org/content/94/24/12744.full.

patentability and subsequent ownership and control of the subject matter is questioned as it reduces human genetic material to mere molecules with recognised properties. Are human genes an intricate part of being human? Do they lose their uniqueness and become different from the human as they are separated from the individual in a lab?

Can human genes as property be alienated and given unto another? Are human genes patentable?

1. a. Patentability of genes in US

United States Code Title 35 - Patents consolidates and gives a comprehensive document regarding patent law in the United States. Section 101 provides for inventions patentable. "Whoever invents or discovers any new and useful process, machine, manufacture or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title." This principle was reiterated in the case of *Diamond v. Chakrabarty*[15], where the respondent's Patent claim for a human made oil eating bacterium was denied by the Patent Office on the basis of unpatentability of life forms. The Court held that the subject matter was patentable under the same Section, as it constituted a "manufacture or composition of matter The bacterium was hitherto unknown, non-naturally occurring organism, "a product of human ingenuity", "having a distinctive name, character and use"[16] in great contrast to the case of *Funk Brothers Seed Co. v. Kalo Inoculant Co.*[17]where the patent claim was to a root nodule bacteria that was already naturally existing. By the judgment in *Diamond v. Chakraborty*, the demarcation between patents on the living and the non-living was crossed. By the same ratio held by the Court in this case any genetic material manufactured and manipulated in the laboratory can be patented granted it holds up to the conditions prescribe in the legislation, this paves the way to the blurring of the line between non-human genetic patents and human- genetic patents.

Section 102 enumerates the conditions for novelty in a patent like absence of any Prior Art[18], not in printed publication or public use or on sale or disclosed otherwise, granted each of the terms has its own exceptions. Section 103 (b) (3) enumerates what biological inventions would be considered

[15] *447 US 303, (1980*).

[16] *Hartranft v. Wiegmann,* 121 U. S. 609, 121 U. S. 615 (1887).

[17] 333 U. S. 127.

[18] USC Section 103(a) on Conditions for Patentability : Non-Obvious Subject Matter states that "prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains."

for Patentability. It reiterates, "Biotechnological process means -

(A) A process of genetically altering or otherwise inducing a single-or multi-celled organism to-

(i) express an exogenous nucleotide sequence,

(ii) Inhibit, eliminate, augment, or alter expression of an endogenous nucleotide sequence, or

(iii) Express a specific physiological characteristic not naturally associated with said organism;

(B) Cell fusion procedures yielding a cell line that expresses a specific protein, such as a monoclonal antibody…."

Hence, under S. 101, "Laws of nature, natural phenomena, and abstract ideas" are not patentable[19] but the application of a law of nature to 'a known structure or process' may deserve patent protection[20]. In addition, such an application must cross over from the realm of literal words of in the patent process to an actual and particular inventive application of the law[21]. In two contrasting cases, *Diamond v. Diehr*[22] and *Parker v. Flook*[23] additional steps integrated with a natural cases allowed the subject matter patentable in the first instance and in the second instance additional processes were not capable of rendering the application particular, new or with any industrial application.

In the case of *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*[24] Prometheus' process concerning the use of Thiopurine drugs to treat autoimmune diseases was held not patent eligible as the laws of nature recited by Prometheus' patent claims—the relationships between concentrations of certain metabolites in the blood and the likelihood that a Thiopurine drug dosage will prove ineffective or cause harm—are not themselves patentable, the claimed processes, also are not patentable unless they have additional features that provide practical assurance that the processes are genuine applications of those laws rather than monopolizing the whole process thereby preventing any other meaningful research and application of the said natural process.

[19] *Parker v. Flook,* 437 U. S. 584 (1978); *Gottschalk v. Benson,* 409 U. S. 63, 409 U. S. 67 (1972); *Funk Brothers Seed Co. v. Kalo Inoculant Co.,* 333 U. S. 127, 333 U. S. 130 (1948); *O'Reilly v. Morse,* 15 How. 62, 56 U. S. 112-121 (1854); *Le Roy v. Tatham,* 14 How. 156, 55 U. S. 175 (1853).

[20] *Diamond v. Diehr,* 450 U. S. 175, 185.

[21] "Phenomena of nature, though just discovered, mental processes, and abstract intellectual concepts are not patentable, as they are the basic tools of scientific and technological work." *Gottschalk v. Benson*, 409 U. S. 63, 71–72.

[22] 450 U. S. 175, 185.

[23] 437 U. S. 584, 590.

[24] 628 F. 3d 1347.

1. b. Patentable Subject-Matter in Europe

In consistence with the aim of free trade and open market that marks the European Union, the Directive 98/44/EC on the Legal Protection of Biotechnological Inventions, 1998 amalgamates and conciliates the differences that exist in the legal protection of biotechnological inventions offered by the laws and practices of the different Member States. However, the Member States are to protect biotechnological inventions under the respective national patent law but encouraged to adjust their national patent law to take account of the provisions of this Directive[25].

Article 3 of the Directive states that:

1. "For the purposes of this Directive, inventions which are new, which involve an inventive step and which are susceptible of industrial application shall be patentable even if they concern a product consisting of or containing biological material or a process by means of which biological material[26] is produced, processed or used.

2. Biological material which is isolated from its natural environment or produced by means of a technical process may be the subject of an invention even if it previously occurred in nature."

The Directive does not allow the patenting of the human body as such or at any stage of its development or the simple discovery of any of its elements, including the sequence or partial sequence of a gene. [27]The exception to this being that human genetic material isolated from the human body or produced through technical process or sequencing or partial sequencing of a gene may be eligible for patenting even if it is identical to the naturally occurring elements[28]granted the industrial application of the sequence or partial sequence of the gene be disclosed in the patent application[29]. Such a patenting is again barred if the commercial exploitation of which is in violation *ordre public* or morality.[30]

Article 6(2) of the Directive expressly prohibits cloning of humans, modification of the germ line genetic identity of human beings and the industrial or commercial use of human embryos.

Article 7 enlists The European Group on Ethics in Science and New Technologies to

[25] Article 15 of the Directive 98/44/EC on the Legal Protection of Biotechnological Inventions, 1998.
[26] Article 2(a) of the Directive 98/44/EC on the Legal Protection of Biotechnological Inventions, 1998 defines biological material as " any material containing genetic information and capable of reproducing itself or being reproduced in a biological system."
[27] Article 5(1) of the Directive 98/44/EC on the Legal Protection of Biotechnological Inventions, 1998.
[28] Article 5(2) of the Directive 98/44/EC on the Legal Protection of Biotechnological Inventions, 1998.
[29] Article 5(3) of the Directive 98/44/EC on the Legal Protection of Biotechnological Inventions, 1998.
[30] Article 6(1) of the Directive 98/44/EC on the Legal Protection of Biotechnological Inventions, 1998.

evaluate all the ethical aspects of biotechnology.

Article 52(1) *of* the EPC (European Patent Convention) deals with "Patentable Inventions' provides susceptibility to industrial application[31] as an important prerequisite. Novelty[32] and inventive step[33] are other conditions. *Human Genome Sciences v. Eli Lilly*[34] analyzed the requirement of industrial applicability in Articles 52 and 57 of the EPC. The patent application described the encoding nucleotide, the amino acid sequence, and certain antibodies, of a novel human protein, which it calls Neutrokine-α contending biological as well as therapeutic uses.

The issue of patentability once examined illustrates that patent of human genes as such and in the world does not have specific and definite set of rules or court rulings setting boundaries between what can be done and what should not be done. It is yet to be fully and manifestly brought to a conclusion. It came close in the case *Moore v. The Regents of the University of California*[35] where the plaintiff Moore, who was under treatment for a rare form of leukemia went to Court claiming rights over a patent on a cell line developed exclusively from blood and tissue samples obtained from Mr Moore without his informed consent. Though the action failed on a technical issue the decision, both concurrent and dissenting, sheds light on the conflict in human gene patenting. The rights of dominion over one's body, and the interests one has therein, are recognized in many cases. These rights and interests are so akin to property interest that it would be subterfuge to call them anything else. The opinion of the Supreme Court demonstrates, however, that the fundamental issue in the Moore case is whether a person has the right to be informed of how tissues that are removed from his or her body will be used

[31] Article 57 of the European Patent Convention "An invention shall be considered as susceptible of industrial application if it can
be made or used in any kind of industry, including agriculture."

[32] Article 54(1) of the European Patent Convention An invention shall be considered to be new if it does not form part of the state of the art.
(2) The state of the art shall be held to comprise everything made available to the public by means of a written or oral description, by use, or in any other way, before the date of filing of the European patent application.
(3) Additionally, the content of European patent applications as filed, of which the dates of filing are prior to the date referred to in paragraph 2 and which were published under Article 93 on or after that date, shall be considered as comprised in the state of the art.
(4) Paragraph 3 shall be applied only in so far as a Contracting State designated in respect of the later application, was also designated in respect of the earlier application as published.
(5) The provisions of paragraphs 1 to 4 shall not exclude the patentability of any substance or composition, comprised in the state of the art, for use in a method referred to in Article 52, paragraph 4, provided that its use for any method referred to in that paragraph is not comprised in the state of the art.

[33] Article 56 of the European Patent Convention "An invention shall be considered as involving an inventive step if, having regard to the state of the art, it is not obvious to a person skilled in the art."

[34] *UKSC 51, 2011.*

[35] 51 Cal. 3d 120, 793.

and disposed of. [36] The Court has answered the question in positive that there must be informed consent, especially regarding the possible commercial application of the tissue so removed.

2. Ethics, order and morality

The big concern before the world today is to set a balance between the patent rights and public order. A patent is a civil right guaranteed to a patentee and once a product is invented, it is important to seek a patent for that invention, in order to prevent its misuse. It is guaranteed to the patentee for an invention to prevent the marketing or selling of the invention, thereby restricting the monetary gains that might rise out of the invention to the inventor alone.

The naturally occurring genomes and human genomes being *res communis* i.e the common heritage and inheritance of mankind has been a debatable issue and therefore many eminent scientists and governments have taken the position that the human genome and other naturally occurring genomes should be devoid of been patented as the patenting of genes would result in widespread misuse of the patent system as it would pave the path towards privatization and commercialization of the common heritage of all humankind that has been inherited from previous generations .

There are two contradicting views regarding the relation of morality or public order with the granting of patents. Though the general view is that patent shall be granted as long as the invention in novel, inventive and useful and morality should have no role to play in the grant of the patent, the natural law presents opposite views that an invention which offends society's morals should not be granted patents as they opine that law is a reflection of morals of the society and something which offends morality of society cannot be given a legal character.

a. Position in TRIPS

Article 27.2 of the Trade Related Intellectual Property rights (TRIPs) allow member countries to exclude form patentability, such inventions, which may offend the morality or public order of the its society. It states:

"*Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect ordre public 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 exploitation is prohibited by their law".*

[36] Maureen S. Dorney, Moore v. the Regents of the University of California: Balancing the Need for Biotechnology Innovation against the Right of Informed Consent, 5 Berkeley Tech. L.J. 333 (1990).

b. Position in United States

The United States of America never had an exception of morality or ordre public in their patent laws. However, such requirement was fixed by the Courts, but the same was used rarely. In the mid twentieth century ,the USPTO(United States Patent and Trademark Office) started banning patents on gambling machine on morality grounds and the same came to end in 1980's when the Court held that inventions for gambling machines are no more or less immoral than invention such as gun which may used for killing people.

The USPTO, by the late nineties, invoked the moral utility doctrine in order to check the controversial applications related to biotechnology inventions. But the same was criticized by the Courts because according to them it is the legislature and not the executive which can define the boundaries of the law. Hence there are very few examples where the morality exception was raised by the USPTO.

c. Position in European Union

The European Union adopted a different approach by inserting the 'morality' and 'public order' clause in the patent laws since the very beginning. Unlike TRIPs, the European Patent Convention mandatorily requires its members to provide for morality exclusions. Further, the EPO(European Patent Office) later on issued Biotech Directive – 98/44/EC which bars certain biotechnological invention derived from the destruction of human embryos or manipulation of genetic structures. EPO is very stringent on this morality and public ordre exclusion and unlike the US, it first asks the question before deciding for the grant of the controversial patents.

Article 53(a) of the European Patent Convention 2000 provides that the European patents '*shall not be granted in respect of inventions the commercial exploitation of which would be contrary to 'ordre public' or 'morality' and that 'such exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the contracting states*"

Under Article 53(a), European patents shall not be granted in respect of biotechnological inventions, which, in particular, concern the following:

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.

Ultimately, for the benefit of humanity as a whole, sometimes we need to neglect the

morality aspect to ensure that researches are conducted in a proper manner.[37]

d. Position in India

The Indian Patents Act, 1970 provides a statutory provision regarding the public order or morality exclusion.

Section 3(b) states that "*an invention the primary or intended use or commercial exploitation of which could be contrary to public order or morality or which causes serious prejudice to human, animal or plant life or health or to the environment*".

Any invention should be novel in that its impugned application should be beneficial to the society as a whole. In the case of *Novartis AG v. UoI & Ors*[38] the IPAB denied patent on the ground that the prices of the drug Gleevec is excessively high and was unaffordable for the poor cancer patients in India.

3. Commercial interest

As new genes continues to be identified and the companies blindly follow the path of monopolisation and commercialization by attaining the sole right over the genetic testing of patented genes, the public interest at large has been deprived as they are denied from accessing vital good quality medicine which are been sold by these companies at expensive rates instead of normative prices that can be afforded by the layman. Moreover, the growing emphasis on patents has created an atmosphere of secrecy among researchers and university researchers often end up with a flair for commercialisation as research in the field of genetics attracts many investors.

4. Research Stagnation

The human DNA symbolizes something essential about humans themselves, and, as such, raises the issue of human dignity.[39] Though the utility and inventiveness associated with patenting genes can be argued at one end, it does not take away the

[37] In the case of Onco-Mouse the exclusion under Article 53(a) of the EPC was argued for the first time. In this case the subject matter of patent application was a mouse which has been genetically modified to carry an oncogene in order to make them more vulnerable to cancer. The object of the invention is to use these modified mice in cancer research. Upon examination of the application the EPO rejected the application stating that the animal varieties are not patentable. However on appeal the Technical Board of Appeal applies the morality clause under Article 53(a). The technical board is of view that genetically modifying a mammal and that to ensure that it will develop cancer was very problematic as the same cause suffering to the animal. However the Board of Appeal forwarded the application back to the examination division stating that while considering morality, the Office should balance inventions utility to the mankind with the suffering caused to the animals. The Board accordingly held the genetically modified mouse to be patentable on the grounds that the same was for the benefit of the humanity.

[38] Civil Appeal No.2706-2716 of 2013.

[39] Ethics and Gene Patenting of SNP,TRIPS and Human Dignity, Miriam Schulman https://www.scu.edu/ethics/focus-areas/bioethics/resources/ethics-and-gene-patenting/.

ultimate truth that the patenting of human genomes is different from other subjects of patent application as by granting of patent to genes, we are preventing the conduct of research.

There is no general statutory exemption for experimental use in the United States, although it has been contested that the basic research is exempt from patent infringement. Although the United States courts recognize a patent exemption for 'philosophical' study, the scope of this exemption is, at best, confusing and, at worst, extremely narrow, leading many commentators to call for an amendment of the patent law itself .

For example, one study of United States life-science faculties found that involvement with industry (which inevitably includes patent considerations) increased the chance that a researcher believed his or her "choice of research topics had been influenced by the likelihood that the results would have commercial application."[40]

Under the European Patent Convention, both commercial and non-commercial research is permitted on the subject matter of a patent. Thus, the situation is clearer for researchers in Europe.[41]

Suggestions

It is the need of the hour to bring about a more structural framework to the issue of gene patenting of human beings so that it will be a revolution in itself which will act as a buffer to prevent genetic disorders and would pave the path for greater advancement in science and thereby the betterment of human race. Some suggestions to improve the present scenario are:

1. ***Need for legal framework***

   There is a need for a definite legal position on human genetic patents through legislation as Courts deciding on these issues as and when they arise is simply not enough. Conflicts that arise are mostly settled out of court and those that go through trial does not give the court enough scope for decision as the Courts have to strictly abide by the issue raised and relief asked for in the suit and nothing else. The legislation if and when formed should cover the whole area of genetic patients from the procedure for sourcing of the genetic material, laboratory trials, approvals and patenting. There should be a process in place to ensure informed consent of the donor

[40] Patenting human genetic material: Refocusing the debate, Timothy Caulfield, E. Richard Gold, and Mildred K. Cho, PMID: 11252752.

[41] *Id.*

regarding the extent of research and any future commercial application in the future. There should be established watchdog organizations both governmental and non-governmental, to keep in an eye on any attempts by any individual or corporate to gain unfair advantages in the name of noble pursuit of human development through science.

2. ***Universality of rules***

The patent regimes in different countries differ widely.(An example is illustrated in the prominence of the "public order and morality" clause regarding patentability in the European union and the lack of such perquisite in the US patent law). Checks and balances on the process of human genetic research and patenting needs to be universally enforced as any imbalance in such enforcement may lead to a lax region-witnessing surge in exploitation like human trafficking, slavery and abuse.

3. ***Enabling knowledge and technology sharing***

Patent aims at protecting the innovative intellects but often degrades to the creation of monopoly and profits. Patents should not interfere with further research and through international covenants and regional legislations, a strong culture of sharing and innovation should be developed. Such technology should not be secluded to an individual country or corporation. Providing technical assistance, capacity building and personnel training and licensing are a few ways to ensure technology sharing without compromising a hard won patent.

Conclusion

"Every advantage in the past is judged in the light of the final issue"

\- ***Demosthenes***

Every issue will have its pros and cons and even patenting of human genes has turned out to be a double-edged sword. Some people see human genetic research as a herald of apocalypse whereas to some other it holds the key to unravel the causes and remedy for an array of disorders, diseases and other human anomalies that overall improves the quality of life and patenting such innovations must be a form of recognition, validation and lead to a more proactive environment and not be narrowed down to mere commercial interest.