DESIGNER BABIES; AN ANALYSIS OF LEGAL FRAMEWORK AND ETHICAL ISSUES SURROUNDING HUMAN GENE EDITING TECHNOLOGY

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Abstract

Human genome engineering and gene editing technologies like CRISPR technology has completely revolutionized human therapeutics, agriculture and the health care industry. With the help of CRISPR technology it is now possible to genetically modify human embryo which in turn has opened the doors to a whole new concept called 'Designer Babies' where the parents can choose or alter certain traits of their unborn child. With the use of an advanced technology like CRISPR; a Parent can now, practically design their baby according to their whims and fancies. However, the process of genetically modifying babies involves altering genes in embryos, eggs or sperm. This type of genetic engineering is potentially heritable, meaning that mutated genes may be passed on to the subsequent generations as well and therefore, by editing the genes of one baby, they are potentially mutating the genes and characteristics of generations of humans.

This brings to the focus the capability or in some cases, incapability of national and international law to regulate research into this unknown but welcome field. It definitely brings to light certain social, ethical and religious concerns surrounding genetic editing which could be passed from one generation to the other. In this article we aim to analyze the legal and regulatory policy that governs the human gene editing, with specific emphasis on its applicability in the production of designer or genetically modified human babies and analyze the legal position of human gene editing in India.

At present The Indian Council of Medical Research or ICMR is the apex body in India for the formulation, coordination and promotion of biomedical research in India. The ICMR has published the National Ethical Guidelines for Biomedical and Health Research on Human Participants, which acts the Guideline for all biomedical research conducted on human participants. The ICMR's Ethical guideline has explicitly prohibited any form of alteration to Human genes. The ICMR has also published the National Guidelines for Stem Cell Research, 2017 which is a set of guidelines that regulate gene editing, human germ line editing, cellular research and cloning in India. According to the guidelines prohibited areas of research includes "Research related to human germ line gene therapy and reproductive cloning "and Use of genome modified human embryos, germ-line stem cells or gametes for developmental propagation. The guidelines set forth by the ICMR prohibit any research or developments in the field of human gene editing but since these are guidelines and not legislation; they lack the force of law and the binding nature of the guidelines are in question. In this article we also dive into the practical enforceability of these guidelines.

Through this research paper, the researcher tries to encourage the CRISPR –CAS9 technology by providing adequate suggestions, as complete prohibition and restriction will only hinder and slow down the new innovations in the field.

Index terms– CRISPR CAS-9, guidelines, genetic engineering, patent.

1. Introduction

Genetic engineering in layman's term is the editing or direct manipulation of an organism's genes to alter the characteristics of that organism in a specific way. Put very simply, it is re-designing the genetic material of a living organism to achieve and/or remove the desired characteristics. Chinese researchers published the result of the first use of gene editing technology in human embryos in 2015; this gene editing technology is known as CRISPR-Cas9[1]. CRISPR is an acronym for "Clustered Regularly Interspaced Short

[1]Puping Liang et al., *CRISPR/Cas9-Mediated Gene Editing in Human*
see also David Cyranoski& Sara Reardon, Chinese Scientists Genetically Modify Human Embryos,NATURE (Apr. 22, 2015), https://www.nature.com/news/chinese-scientistsgenetically-modify-human-embryos-1.17378#/bl.

Palindromic Repeats." Human genome engineering and gene editing technologies like CRISPR technology has completely revolutionized human therapeutics, agriculture and the health care industry. Advanced gene editing methods like CRISPR technology has the potential to become the next big thing in Medical Research. With the help of CRISPR technology, it is now possible to genetically modify human embryo which, in turn has opened the doors to a concept called 'Designer Babies' where parents can choose certain traits of their unborn child and can practically design their babies before its birth. This technology has paved the path for the mass scale production of genetically modified products in a cost effective manner, thereby opening the possibilities of gene editing technology to the general public; it is no longer confined to the research facilitates and laboratories.

With the use of new ground breaking technology likeCRISPR-Cas9 technique, scientists can now design or re-design babies; they have the ability to pick and choose characteristics of an unborn baby. This technology gives them the ability to remove potential genetic defects and disease causing genes and thereby making healthier and genetically superior progeny. Rapid changes like this in the biotechnology industry bring to focus the inadequacy or inefficacy of laws regulating this field both nationally and internationally. It also brings focus to the moral, ethical and religious issues entwined with human gene editing.

2. Analysis of Legal and Regulatory Framework in India

The Indian Council of Medical Research or ICMR for short is a government organization and is the apex body in India for the formulation, coordination and promotion of biomedical research. The ICMR has published the National Ethical Guidelines for Biomedical and Health Research on Human Participants, which acts the Guideline for all biomedical research conducted on human participants. The ICMR's Ethical guideline has explicitly prohibited any form of alteration to Human genes; it clearly states that "Eugenic genetic engineering for changing/selecting/altering genetic characteristics and creating so called designer babies is prohibited. These should not be attempted, as we possess insufficient information at present to understand the effects of attempts to alter/enhance the genetic machinery of humans. It would be unethical to use genetic engineering for improvement of intelligence, memory, formation of body organs, fertility, physical, mental and emotional characteristics, etc. even if specific gene/genes are identified in future."[2]Therefore the primary obstacle in the way of conducting Human gene editing in India is the prohibitory clause in the Ethical Guideline made by the ICMR.

The ICMR along with the Department of Biotechnology, Ministry of Science & Technology has also published the National Guidelines for Stem Cell Research, 2017which is a set of guidelines that regulate gene editing, human germ line editing, cellular research and cloning in India. According to the guidelines prohibited areas of research includes "Research related to human germ line gene therapy and reproductive cloning"[3] and Use of genome modified human embryos, germ-line stem cells or gametes for developmental propagation.[4] Further the guidelines also state that "*In-vitro* studies can only be conducted on spare embryos, germ-line cells or gametes. Further, "the genome modified human embryos should not be cultured beyond 14 days of fertilization or formation of the primitive streak, whichever is earlier to ensure that these embryos should not have a possibility of being inserted into the womb"[5]

It is very clear from the ICMR Guidelines that India categorically prohibits research involving implantation of human embryos after *in vitro* manipulation, at any stage of development, into uterus in humans, the guidelines also prohibit human germ-line gene therapy. However, the real question here is the enforceability of the ICMR guidelines and does it have the force of law? And what are the repercussions of disobeying these guidelines? Since these guidelines are not backed by legislations they fall under the category of non-mandatory guidelines. What is the consequence of disobeying the guidelines laid down by the ICMR?

Disobeying the guidelines is considered unethical practice and amounts to professional misconduct[6]. Any medical practitioner found guilty of professional misconduct under the Medical Council (Professional conduct, Etiquette and Ethics) Regulations, 2002 can be removed from the register of the medical council of India and therefore shall be deemed ineligible from practicing medicine there forth. Therefore, the ICMR guidelines can be enforced through indirect means only, the guidelines may find force through a coercive order of the professional association like the medical council of India.

At this stage it is very clear that any research or studies in the field of human gene editing and the use of CRISPR technology for genetically altering DNA is prohibited by the ICMR. However the guidelines lack legislative sanction required to make it mandatory. The prohibition of research in this field is mainly in place because of the lack of understanding about the long term effects of this technology, the fear of misuse of CRIPR technology is one of the main causes of for this prohibition.

[2]Clause 10.14.8 National Ethical Guidelines for Biomedical and Health Research Involving Human Participants (2017)
[3]Clause8.3.1 The National Guidelines for Stem Cell Research, 2017"Guidelines"
[4]Clause8.3.5 The National Guidelines for Stem Cell Research, 2017"Guidelines"
[5]Clause 8.3.2. The National Guidelines for Stem Cell Research, 2017"Guidelines"

[6]Clause 7.22 of CMER

3. **Are Human Genes Patentable?**

Since genetic material and DNA are natural occurring substances and the manipulation of such natural occurring substance to get the desired results posts a legal and ethical conundrum; Gene and nucleic acid based patents, specifically, have been in the midst of controversy in the recent years around the world[7].A gene patent grants exclusive rights of specific sequence of DNA to an individual, organization, or corporation who claims to have first identified the gene. Once the gene patent is granted, the holder of the patent has monopoly over its rights and can dictate how the gene can be used, in both commercial settings, such as clinical genetic testing, and in noncommercial settings, including research, for 20 years from the date of the patent. Gene patents have often resulted in companies having sole ownership of genetic testing for patented genes.[8]

In India under Section 3(c) of the Patents Act 1970 it specifies that the mere discovery of a scientific principle or the formulation of an abstract theory, discovery of any living thing or non-living substance occurring in nature would not be patentable, according to this section mere discovery or isolation of genes that exists in nature cannot be patented, but that leads to the question whether isolated and synthesized DNA can be patented? Unfortunately, there is lacuna in judicial decisions with respect to this subject matter. In 2010, Patent was granted to Genetically Stable JEV cDNA based on Japanese Encephalitis Virus (Patent No. 243799) by the IPO, the patent was granted for the protection of a cDNA sequence, though it was not synthesized or a recombinant and a mere derivative of the exiting natural sequence. In another instance an Expression Vector or Cloning Vector Encoding Filarial Parasite Polypeptide (Patent No. 246865)[9] was granted patent in 2011, in the initial stage the patent office had objected to the patent stating that a cDNA sequence was obtained from what was already existing in nature. Subsequent claims based on RNA and the polypeptides were also subject to the 3(c) objection. But ultimately these objections were withdrawn and the patent was granted.

In March 2013, a set of Guidelines for Examination of Biotechnology Applications for Patent was published by the office of the Controller general of patents, designs and trademarks. The guidelines expressly state that sequences isolated directly from nature are not patentable, subject matter which is the correct interpretation of Section 3(c) of the patents act 1970. The guidelines were made with a view to make uniform and consistent practices in granting of biotechnology patents. However there guidelines do not constitute rule making. Therefore In case of any conflict between the guidelines and any of the provisions contained in the Patents Act, 1970 and the Patents Rules, 2003, the provisions of patent Act and Rules will prevail over the guidelines.

Under section 3(j), animals, plants, or part thereof, not only of the natural origin but such living entities of artificial origin such as transgenic animals and plants or any part thereof are also not patentable. Microorganisms may be construed as being patentable as per section 3(j), however section 3(j) read together with section 3(c) makes it clear that naturally occurring isolated microorganisms are not patentable subject matter in India. Nonetheless, genetically engineered or modified micro-organisms of artificial origin and vaccines are considered patentable.

At the present stage there is no uniformity and lacuna in judicial decisions with respect to patentability of human genes. The inconsistencies and disparities in granting of patents must be dealt with as incorrectly granted patents will only hinder innovation in this area. In the event that a patent has to be granted to human genes, it has to be to be for a sequence of gene or DNA that is invented or synthetized (not natural). It has to show enhanced effects or benefits when compared to that in nature or for a sequence having a novel application.

In the case of the Association for Molecular Pathology v. Myriad Genetics, Inc., the Supreme Court of the United States ruled that human genes cannot be patented in the U.S. because DNA is a "product of nature" and not something created in a laboratory, mere isolation of a sequence of a gene would not qualify for a patent[10]. The Court found that the location and the sequence of the gene existed in nature even before the patentee had discovered the gene. The patentee could not claim that they had created the gene; there was no invention of a new genetic structure. The patentee could only claim the identification of the exact location and sequence of the gene. The Court decided that a patent cannot be granted to a naturally occurring substance. Therefore Human genes cannot be patented unless a new gene or DNA sequence is created by the inventor. It is also to be noted that prior to the Myriad Genetics case, more than 4,300 human genes were patented, and the decision in Myriad Genetics case invalidated all prior gene patents.

4. Moral and Ethical Issues

Apart from the serious legal restrictions in place there are a large number of ethical and moral problems posed by this idea of creating designer babies. One of the biggest concerns about this technology is that whether the genetically modified genes would transfer their altered traits to the next generation and there by changing the genetic structure and in turn, the characteristics of

[7]https://www.nature.com/news/the-great-gene-patent-debate-1.11044, *The Telegraph*, 5 August 2011, http://www.telegraph.co.uk/health/8684001/NHS-hospitals- face-DNA-patent-law-suits.html and Caulfield Policy conflicts: Gene patents and health care in Canada, http://www.ncbi.nlm.nih.gov/pubmed/16244476.

[8] https://ghr.nlm.nih.gov/primer/testing/genepatents

[9] Noordin R, Abdullah K A, An expression vector or cloning vector encoding a filarial parasite polypeptide, Indian Patent No. 246865 (Universiti Sains Malaysia) (18 March2011).

[10]https://ghr.nlm.nih.gov/primer/testing/genepatents

humans for multiple generations[11]. Would these superior traits such as increased intelligence, memory, height, disease-resistance etc. create a distinction between normal humans and genetically altered humans? Mutations form one generation can be transferred from one generation to the other. Would the genetically engineered humans be superior to normal humans? Another concern is that the baby that is being designed by its parents does not have any involvement in choosing the characteristics that he/she will ultimately possess. Some parents would be inclined to making their child look more beautiful and would concentrate on external features of the human body while other parents may concentrate more on the intelligence of the child, either way the child does not get to choose his/her characteristics. This leaves room for difficult ethical and moral questions that ought to be answered by the creators. In addition to the ethical and moral issues behind this technology many individuals have a negative reaction to the use of gene editing in human embryos for religious reasons as well. Many individuals believe that it is against the will of god to alter human characteristics and that humans ought to remain as god made us.

The Moral Utility Doctrine is a loosely-defined nineteenth century common law doctrine that allows the courts to consider if an invention is injurious and against morality of the society. This doctrine gives the judiciary the power to identify if an invention is injurious to the society[12]. However, the moral utility doctrine was considered inconsistent even before its current dormancy[13]. The moral utility doctrine was an inconsistent system of ethical regulation, as it did not have uniformity in its application. Often times the applicability of the doctrine depended solely upon the judge's individual views and was not reflective of the society's view as a whole.

International intellectual property agreements like the Trips Agreement acknowledge that there are ethical and moral exceptions to patent subject matter eligibility. The trips agreement allows member countries to exclude certain inventions from patentability, in order "to protect *ordre public* or morality, these including protecting human, animal or plant life or health or to avoid serious prejudice to the environment."[14] Additionally, the European Patent Convention requires its member countries to exclude patents that would be "contrary to '*ordre public*' or morality." [15]The approaches in international treaties may differ, but each indicates at least the recognition of the role that moral and ethical concerns could play in the signatories' patent process. Ultimately, although gene editing in the age of CRISPR-Cas9 has the potential for immense public benefit, the corresponding ethical considerations may hinder its benefits and public perception if not adequately acknowledged.

4. Conclusion and Suggestions

CRISPR-Cas9 is a revolutionary technology that has the potential to single-handedly change the biotechnology industry as we know it. With the rapid changes in the field of biotechnology and gene editing the law often times fail to keep up with this fast paced industry. Complete Prohibition and restriction on the use of such radical and path paving technology will only hinder and slow down the new innovations in this field.. Designer babies or editing human genes may not seem like a good idea at the first glance but the fact that we humans have developed technologies that can edit our own genes is impressive in itself and Absolute prohibition in these areas would be catastrophic for new inventions in this area of study. With the help of CRISPR and other gene editing technology, scientists now possess the power to eradicate certain genetic disorders, increase human intelligence, memory, height etc. New laws have to be created so as to allow research in this field. Creation of a new legislation specifically for the purpose of research in human gene editing may be the key to this problem. The government can authorize laboratories where research in this field is allowed, the approved laboratories must be in close observation and supervision of government officials. The government can also appoint an ethics committee comprised of scientists and judges to prevent unethical practices with regard to designer babies.

If science is not allowed to live, it will die an untimely death.

[11]https://www.theguardian.com/science/2017/jan/08/designer-babies-ethi-cal-horror-waiting-to-happen

[12] Lowell v. Lewis, 15 F. Cas. 1018, 1019 (C.C.D. Mass. 1817

[13] Andrew Smith, *Monsters at the Patent Office: The Inconsistent Conclusions of Moral Utility and the Controversy of Human Cloning*, 53 DEPAUL L. REV. 159, 161 (2003).

[14]*See* Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994).

[15] The European Patent Convention art. 53, Oct. 5, 1973, 1065 U.N.T.S. 199 (revised at the Convention on the Grant of European Patents Nov. 29, 200).