Page 3320 - 3334 **DOI:** *https://doij.org/10.10000/IJLMH.117332*

INTERNATIONAL JOURNAL OF LAW MANAGEMENT & HUMANITIES

[ISSN 2581-5369]

Volume 7 | Issue 2

2024

Designer Genes: A Glimpse into The Future of Human Potential

NAMANA SHREYA ARCHALA SAI[1] AND KAVYA SRI POTHULA[2]

ABSTRACT

Genetic engineering has been rapidly developing in the biotechnology industry. With the advent of this technology that uses techniques like CRISPR, the concept of designer baby has become a reality. This CRISPR helps in customizing the traits of the foetuses by using the cut and paste of DNA method. Even though it has many notable benefits, it should be considered that it is associated with several ethical and legal concerns. Since it is a new development, it has no proper legal framework in existence, hence it is essential to address these matters. The legal positions of several nations such as USA, UK, India and others have been discussed in this article. In India, even though there is no proper legislation that regulates this process, there are several guidelines given by some government authorities. This article concludes with several recommendations for the regulation of genome editing.

Keywords*: Genetic Engineering, Biotechnology Industry, Designer Baby, CRISPR, Government authorities.*

I. INTRODUCTION

Genetics is the biological study that focuses on the inheritance of traits from the parent organisms to their progeny i.e., the heredity. It involves the study of genes, DNA and genetic inheritance which form the components of genetics.[3]

The swift developments in technology have led to the development of biological technologies with respect to genetic engineering. The process of making modifications or alterations to the components of genetics like DNA, genes, chromosomes is called genetic engineering. Laboratory based technologies are used to make alterations to the DNA and genes. For instance, a gene from one species can be added to another species which in turn modifies its DNA to produce the desired traits. [4]

Gene editing technologies are being developed for the purpose of providing therapy to treat

[1] Author is a student at ICFAI Law School, Hyderabad, India.
[2] Author is a student at ICFAI Law School, Hyderabad, India.
[3] Introduction to genetics, Basic Biology (Aug.31, 2020), https://basicbiology.net/biology-101/introduction-to-genetics.
[4] Mike Smith, Genetic Engineering, National Human Genome Research Institute (Oct. 20, 2023), https://www.genome.gov/genetics-glossary/Genetic-Engineering.

 [ISSN 2581-5369]

humans from a wide range of conditions like cancer, haemophilia etc. [5] Genome editing procedures like Clustered regularly interspaced palindromic repeats (CRISPR) technology could be the upcoming trend in medicinal research. The concept of "Designer Babies" has become a reality due to the ability to genetically alter human embryos through the use of CRISPR technology. These are the offspring that result from the genetic alterations that are made to embryos in vitro which means outside of the human body. This allows parents to essentially create and alter their child's features or traits before they are born.

The initial application of CRISPR-Cas91 gene editing with regards to human embryos was reported by Chinese researchers in 2018. Two embryos were used in an experiment where the embryos' DNA was altered to allow them for fertilization. The two babies, were prematurely born twin girls who are publicly referred to as Lulu and Nana and their present health status is unknown. [6]

Agriculture, the health care sector, and human pharmaceuticals have all undergone complete transformations owing to advances in genome engineering and gene editing tools like CRISPR.[7]

However, the use of such technology has significant social, political, and societal repercussions that should necessarily be considered because it touches on a number of issues, for instance the rights of the people with some incapacities, women, racial justice, environmental justice, and health justice due to which it has been prohibited in several countries across the oceans. [8]

The swift developments in the biotechnology industry demonstrate how inadequate and ineffective national and international regulations are at present in this domain. It outlines the moral and legal concerns surrounding the legitimate use of human gene editing approaches.

II. CRISPR (Clustered Regulatory Interspaced Short Palindromic Repeats)

Genes are the functional unit which are composed of DNA. It can control features like eye colour, height etc. DNA acts as the instruction manual for an organism. In people, it is inherited from our parents. When a new human is brought to life the foetus gets the genes from each set of parents, which in turn will create a new set of instructions and it is restructured in each generation but there is a possibility that these instructions to carry errors which lead to faulty

[5] What is Human Gene Editing?, Centre For Genetics and Society (Sept. 17, 2018), https://www.geneticsandsociety.org/internal-content/what-human-gene-editing.
[6] What is Human Gene Editing?, Centre For Genetics and Society (Sept. 17, 2018), https://www.geneticsandsociety.org/internal-content/what-human-gene-editing.
[7] Sruti Ravindranathan, Designer Babies; An Analysis Of Legal Framework and Analysis and Ethical Issues Surrounding Human Gene Editing Technology, 6 JETIR 405, 405-406 (2019).

 [ISSN 2581-5369]

genes which causing serious illnesses. The sequence they possess repeats themselves multiple times often in reverse order. A class of enzymes identifies specific repetitions in DNA and uses CRISPR technology to cut the DNA and insert crucial information in the middle. These insertions, known as spacers, contain the genetic code of several viruses that have previously infected a host. These earlier invasions have had an evolutionary role in safeguarding the host against such outside threats.

Complementary RNA binds to viruses that carry a matching template sequence and directs a group of CRISPR-associated enzymes or Cas enzymes to locate and cut the invasive DNA at the binding location. This neutralises the threat posed by viruses.

We can modify a cell's genetic code as needed thanks to the extremely efficient and manageable CRISPR Cas technology. But scientists have been wary in the context of the human genome. The act of modifying our own DNA could potentially lead to more challenges than solutions. While Cas9 consistently cuts DNA where intended, recent experiments have shown its potential to affect genes located at a distance from the target. Furthermore, a number of specialists have raised ethical concerns regarding the use of this technology for goals like eugenics and the development of designer babies, even in the unlikely event that we could consistently produce the desired outcomes. There would be serious moral conundrums if parents could eventually afford to hire scientists to modify their child's DNA to increase strength or IQ. Also, the world may become more unfair and biased.[9]

Base editing

It lets scientists to precisely make alterations to a single DNA nucleotide, with greater accuracy compared to CRISPR-Cas9, which can lead to unintended DNA changes. However, using base editing is more complex than using CRISPR-Cas9.[10]

Prime editing

It permits scientists to make precise DNA modifications, including insertions and deletions, and is more user-friendly than base editing, although with a slightly lower level of precision.[11]

[9] Laura Hercher, A New Era of Designer Babies May Be Based on Overhyped Science,Scientific American, July 12,2021,https://www.scientificamerican.com/article/a-new-era-of-designer-babies-may-be-based-on-overhyped-science/

[10] Base editing:What is it and what does it mean for healthcare?,Genomics Education Programme,February 3 2023, https://www.genomicseducation.hee.nhs.uk/blog/base-editing-what-is-it-and-what-does-it-mean-for-healthcare/

[11] Justin A. Bosch, Precise genome engineering in Drosophila using prime editing,PNAS, December 21, 2020, https://www.pnas.org/doi/10.1073/pnas.2021996118#:~:text=Abstract,has%20low%20off%2Dtarget%20effects.

 [ISSN 2581-5369]

III. BENEFITS

Shielded From Sickness

The fundamental internal source for a disease to develop is linked to the genes present in the body. This technology, by altering the genetic composition by cut and paste method will help in treating such diseases. 1 out of every 10 people are affected by an illness which impact their quality of life.

To cite a situation: A baby's survival chance can be increased simultaneously the probability of being affected to a specific health situation can be decreased. Designer babies exhibit a strong resistance to diseases, including cancer.

A disease called Cystic fibrosis causing lung infection can also be cured by replacing the mutated gene.[12] Hence this pathway will stop this kind of suffering.

Tailored Organ Pairing

The mortality rate due to unavailability of organs is very huge. By using genome engineering a genetic profile can be created to match the required organs which in turn will make the process simpler. Modified DNA pieces can be amalgamated into the gene using click chemistry reaction in this technology.

Curate Attributes

This may sound quite impossible but by using this technology parents can actually customize the physical traits of the baby like the height, skin colour, shape etc and traits like intelligence. The gender can also be selected by the parents, therefore because of all these customizations available it is rightly termed as designer babies.[13]

Enhancing Medication For More Effective Treatments

Genome sequencing has the capacity to transform the treatment for illnesses. Unlike the historical one-size-fits-all approach to medication, we can now personalize treatments based on an individual's unique genetic composition. This rapidly evolving field within the medical domain holds the promise of reshaping the way we address various diseases.

Enhancing The Criminal Justice System

[12] About Cystic Fibrosis, CYSTIC FIBROSIS FOUND., https://www.cff.org/What-isCF/About-Cystic-Fibrosis/
[13] Sunny S. , Designer Babies, The Key To A Better Developed World,Seisen International School, FEB 7 2020, HTTPS://WWW.SEISEN.COM/STUDENT-LIFE/SEISEN-POST/FEATURES/~BOARD/SEISEN-POST/POST/DESIGNER-BABIES-THE-KEY-TO-A-BETTER-DEVELOPED-WORLD#:~:TEXT=WHEN%20USING%20THE%20GENETIC%20MODIFICATION,CHANCES%20OF%20SURVIVAL%20AS%20WELL.

 [ISSN 2581-5369]

DNA fingerprinting, a technology stemming from the Human Genome Project, serves as a method for recognizing individuals through their DNA. This technique finds applications in various sectors, particularly in the realm of criminal justice. The utilization of the DNA fingerprinting in the criminal justice system leads to a dependable means of suspect identification, the exoneration of innocent individuals, and the resolution of previously unsolved cold cases. This technology contributes significantly to the improvement of criminal justice proceedings.

Economic Success Of The Human Genome Project

The Human Genome Project (HGP) proved to be a highly productive economic endeavour, employing more than four million individuals and generating nearly $1 trillion in economic stimulus. Its enduring effects continue to give rise to new industries and job opportunities in the fields of science and medicine.

Broad-Reaching Benefits of The Human Genome Project

The HGP's influence extends beyond humans, benefiting various other living organisms as well. Through an understanding of the human genome, we've harnessed similar principles to enhance the genomes of animals and plants. This knowledge contributes to the development of healthier crops and livestock, as well as the eradication of diseases that significantly impact agriculture.[14]

To conclude, the Human Genome Project has left a substantial and positive imprint on the economy and the overall health and prosperity of humans and other living entities.

IV. MEDICAL INVENTIONS

A team headed by He Jiankui leads employed CRISPR gene-editing technology with the goal of averting diseases in infants. Chinese researchers originally amended the genes of a human embryo within a laboratory environment in 2015. The study that uses CRISPR to modify human embryos prior to their implantation into women's uteruses is described in the clinical trial materials.

He Jiankui spoke at a scientific meeting at Cold Spring Harbour Laboratory in 2017 and talked about a number of preliminary studies that were carried out on mice, monkeys, and over 300 human embryos. These results were also posted on YouTube. The possibility of accidental mutations is a major worry with CRISPR technology, but He claimed to have seen few to no unwanted alterations in the test embryos. Not only is he a researcher, but he is also the founder

[14] Louise Gaille , 10 Human Genome Project Pros and Cons,Vittana.org, May 12, 2018 , https://vittana.org/10-human-genome-project-pros-and-cons

and chairman of Direct Genomics, a DNA sequencing firm. Adoption of novel approaches to enhance children's health might result in significant financial gains for startups in the biotechnology sector.

The National Academies of Science, Engineering, and Medicine hosted an inaugural International Summit on Human Gene Editing in December 2015 in Washington, D.C., and the second summit was hosted in November 2018 in Hong Kong. The clinical study design entails genetic evaluations of the embryos along with continuous foetal development monitoring. He addressed the possible disastrous effects of health problems for the first CRISPR-edited infant during his 2017 presentation. He stressed on the importance of a cautious and deliberate approach, as a single failure could have severe repercussions for the entire field of gene editing.

It's important to remember that utilising genetically modified embryos to create pregnancies is now forbidden in the US and unlawful in many European nations. According to a 2003 ministerial guideline to in vitro fertilisation (IVF) clinics, China has additional regulations in place. It's unclear if He Jiankui followed this advice—which might not have legal weight—or if he had special approval. [15]

US researchers have developed a new technique for making precise changes to DNA without the need for cutting it. This method, which is more precise than CRISPR-Cas9, presents increased complexity in its application. It holds promise for addressing genetic defects in human embryos without causing unintended consequences.[16] In 2020, scientists in the United States reported their achievement in using base editing to correct a genetic mutation that leads to a rare form of muscular dystrophy in human embryos. This was the first instance base editing repaired a genetic abnormality in US human embryos.

V. LIMITATIONS

Since genetic engineering techniques are still in their experimental stages, much more research and analysis are required to determine their long-term efficacy and safety.

The complexity of genes makes gene alterations very erroneous, particularly when one gene is involved in numerous features or when multiple genes effect a single feature.[17]

[15] Antonia Regalado, Chinese scientists are creating CRISPR babies,MIT Technology Review,November 25,2018, https://www.technologyreview.com/2018/11/25/138962/exclusive-chinese-scientists-are-creating-crispr-babies/#:~:text=A%20daring%20effort%20is%20under,been%20tailored%20using%20gene%20editing.

[16] Tanya Lewis , New Gene-Editing Tool Could Fix Genetic Defects—with Fewer Unwanted Effects,Scientific American, October 21, 2019, https://www.scientificamerican.com/article/new-gene-editing-tool-could-fix-genetic-defects-with-fewer-unwanted-effects1/#:~:text=In%202016%20a%20team%20led,relying%20on%20double%2Dstranded%20breaks.

[17] Rohit Garoo, Rebecca Malachi,ed., What Is A Designer Baby And Is It Ethical? Pros And Cons, Mom Junction

This reduces the accuracy and viability of programming the desired features into the embryos.

Apart from the legal restrictions and limitations, the method of genome engineering in order to make designer babies give rise to a wide range of moral and ethical issues.

Since this might change human genetic composition and phenotype over multiple generations, one of the key problems surrounding this approach is whether the genetically changed genes will pass on their altered attributes to the kids. A division between genetically modified and normal humans will arise in society if the mutations are able to be passed down from one generation to the next. [18]

Gene editing causes social problems since it exacerbates the health disparity that exists between rich and poor people in society and beyond national borders. Additionally, it separates people based on their socioeconomic status into those who can and cannot afford to choose for desirable qualities in their future generations. As a result, genetic divisions will develop following the economic divisions. Moreover,a child's experiences and surroundings greatly influence how their personality develops. However, if parents are allowed to choose a baby's traits prior to birth, this limits the natural personality evolution of the child and reduces the influence of multiple factors. Since CRISPR-Cas9 technologies could result in mutations that are handed down from one generation to the next, there is further concern about the potentially harmful, permanent, and unpredictable changes to human genetics that may arise from their application for non-therapeutic purposes.

Based on various religious beliefs, some members of society have an adverse perception of this method. Many believe that the birth of a human is the will of God and making alterations to the human characteristics is going against such will. And that people should continue to be born and remain the way God intended them to be.[19] Also, there are moral and ethical limitations on what qualifies as patentable subject matter, as recognised by international intellectual property accords such as the Trips Agreement. 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," [20]member nations are permitted under the trips agreement to prohibit specific ideas from patentability.

(Jul. 12, 2023), https://www.momjunction.com/articles/designer-babies_00395977/#is-it-ethical-to-produce-designer-babies.

[18] Sruti Ravindranathan, Designer Babies; An Analysis Of Legal Framework and Analysis and Ethical Issues Surrounding Human Gene Editing Technology, 6 JETIR 405, 405-406 (2019).

[19] Sruti Ravindranathan, Designer Babies; An Analysis Of Legal Framework and Analysis and Ethical Issues Surrounding Human Gene Editing Technology, 6 JETIR 405, 405-406 (2019).

[20] Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Article 27, Annex 1C, 1869 U.N.T.S 299, 33 I.L.M 1197 (1994).

 [ISSN 2581-5369]

While the CRISPR-Cas9 era of gene editing has enormous promise for everyone, the benefits are limited by moral dilemmas and negative public attitudes.

VI. INTERNATIONAL LAWS

The United Nations Educational, Scientific, and Cultural Organization's (UNESCO) Universal Declaration on Human Genome and Human Rights is the first international law that regulates this subject. While acknowledging the relevance of the human genome along with its ethical, legal, and societal repercussions, it places an emphasis on the defence of human rights and dignity. Under Article 12, which stipulates that all people ought to have access to advancements in genetics and medicine related to the human genome, this statement permits modifications to the human genome. [21] It allows for modifications made for scientific and medical reasons in an effort to alleviate suffering and enhance people's health.

According to Article 24, working with germ cell lines might be viewed as a practise that goes against human dignity. The term "may" in this article suggests that this proclamation just places limitations on it rather than outright banning it. [22]

Thus, it cannot be said with certainty that the declaration forbids any kind of genetic modification of reproductive cells; rather, it must be acknowledged that such modification can be performed and may not create a harm to human dignity (humanity). [23]

Another regulation pertaining to acknowledgment of the genome as a general welfare is the Convention on Human Rights and Biomedicine, often referred as the Oviedo Convention. It is the Convention for the Protection of Human Rights and Dignity of the Human Being in regard to the Application of Biology and Medicine.

As stated by Article 13, an intervention that leads to a change in the human genome may be utilised only for diagnostic or therapeutic purposes provided it has no intention of changing the genetic make-up of the progeny in a hereditary way.[24] In 2015, the International Bioethics Committee suggested that all signatory countries impose a temporary embargo on germline editing. The report states that "uncertainties on the effect of germline modification on the future

[21] Universal Declaration on the Human Genome and Human Rights of United Nations Educational, Scientific and Cultural Organisation (UNESCO) art. 12, Nov. 11, 1997

[22] Universal Declaration on the Human Genome and Human Rights of United Nations Educational, Scientific and Cultural Organisation (UNESCO) art. 24, Nov. 11, 1997

23 Dorota Krekora-Zajac, Civil liability for damages related to germline and embryo editing against the legal admissibility of gene editing, Humanitites & Social Sciences Communications (Feb. 25, 2020), https://www.nature.com/articles/s41599-020-0399-2#citeas.

[24] The Convention for The Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine, art. 13, April, 4, 1997.

generations" are the grounds for the restriction on gene editing.[25]

The Convention on Human Rights and Biomedicine (1997), defines guidelines aimed at safeguarding human rights and dignity in biology and medicine, including the application of genetic modifications. The 2003 International Declaration on Human Genetic Data demands that genetic information on an individual be protected and used in a way that upholds human rights and ethical standards. [26] The significance of sustainable development and the obligation of the current generation to conserve resources for future generations are emphasised in the UNESCO Declaration on the Responsibilities of the Present Generations towards Future Generations (1997).[27]

(A) United States Of America (USA)

In a report on human genome editing science, ethics, and governance, the National Academy of Science which advises the US government on scientific matters suggested that gene editing research trials should only be permitted if they are used to treat serious disabilities and that they should be carried out under close supervision.

According to the report, germ-line editing is only acceptable in specific situations, such as when there are no other alternatives, when preventing a major disease or illness, during studies involving research for participants' health and safety, etc.[28]

It was made very clear that using gene editing for anything other than treating disabilities would not be permitted.

The National Institutes of Health declared in 2016 that it would not support or permit the use of gene editing involving a process that modifies an individual's genetic makeup in reproductive cells in order to alter a set of genes that are passed onto offspring.

(B) United Kingdom (UK)

Compared to other countries, the UK has taken a more liberal stance on germ line gene editing. While using human embryos, sperm, or eggs with altered genomes for research purposes is

25 Dorota Krekora-Zajac, Civil liability for damages related to germline and embryo editing against the legal admissibility of gene editing, Humanitites & Social Sciences Communications (Feb. 25, 2020), https://www.nature.com/articles/s41599-020-0399-2#citeas.

26 S.Srinidhi et al, The Legal Implications of Gene Editing and Designer Babies in India, 11 IJARESM 501, 503 (2023).

27 S.Srinidhi et al, The Legal Implications of Gene Editing and Designer Babies in India, 11 IJARESM 501, 503 (2023).

28 National Academies of Sciences, Engineering, and Medicine; National Academy of Medicine; National Academy of Sciences; Committee on Human Gene Editing: Scientific, Medical, and Ethical Considerations. Human Genome Editing: Science, Ethics, and Governance. Washington (DC): National Academies Press (US); 2017 Feb 14.

acceptable, using these embryos for assisted reproduction is illegal. [29]

The Human Fertilisation and Embryology Act of 1990 governs about embryonic research in the UK. This law only allows research on embryos under certain conditions, such as requiring a license and prohibiting the keeping of the embryos for a period longer than 14 days or transferring them into a woman's uterus.[30]

In 2016, the Human Fertilisation and Embryology Authority authorised scientists based in London to modify genes that are active during the early stages of fertilisation in human embryos that are viable. The embryos were to be destroyed after the seven days that the researchers were allowed to conduct the tests. Although they won't be the basis of a therapy in and of themselves, the genetic changes may aid researchers in creating remedies for infertility. With this clearance, a national regulatory body has given its support to the first genome editing research endeavour ever. The United Kingdom's approval of gene editing has been developing at an amazing rate.

The Nuffield Council on Bioethics, the UK's ethics body, released a report in July 2018 titled "Genome editing and human reproduction: social and ethical issues." The report's findings suggested that, under certain conditions, using genome editing interventions to modify the traits

(C) India

The highest authority in India overseeing biomedical research is the Indian Council of Medical Research (ICMR). The primary obstacle to genome modification in India is the prohibition included in the ICMR Ethical Guidelines. Any kind of biomedical study that involves human subjects must necessarily adhere to the National Ethics Guidelines for Biomedical and Health study on Human Participants that is published by the ICMR. These rules make it clear that making alterations to human DNA is prohibited. It states that, "Eugenic genetic engineering for changing/selecting/altering genetic characteristics and creating so-called designer babies is prohibited."[31] And that attempts for the same shall not be done as there is no complete information to fully understand that ramifications of trying to alter or enhance human genetic circuitry. Even if a specific gene or genes are finally found, it would be immoral to utilise genetic engineering to improve fertility, IQ, physical, mental, and emotional traits, and other features.

[29] Manuj Borkar, Designer Babies and the Cradle of Legal Framework, The Law Blog (Sep. 27, 2020) https://thelawblog.in/2020/09/27/designer-babies-and-the-cradle-of-legal-framework/comment-page-1/#_ftn4.
[30] Human Fertilisation and Embryology Act, 1990 c. 37, Schedule 2, https://www.legislation.gov.uk/ukpga/1990/37/schedule/2.
[31] National Ethical Guidelines for Biomedical And Health Research Involving Human Participants, Indian Council Of Medical Reasearch, 2017 clause 10.14.8, https://main.icmr.nic.in/sites/default/files/guidelines/ICMR_Ethical_Guidelines_2017.pdf.

Moreover, the Department of Biotechnology, Ministry of Science & Technology, and the ICMR issued the National Guidelines for Stem Cell Research, 2017 a set of regulations governing gene editing, cloning, human germline modification, and cellular research in India. These prohibits use of gametes, germ-line stem cells, and genetically modified human embryos for the purpose of developmental propagation. They also prohibit research on "human germ line gene therapy and reproductive cloning."[32] Additionally, the rules specify that "Only spare embryos or germline cells may be used for in-vitro studies." [33]

In order to prevent the potential of these embryos being placed into the womb, the genome-altered human embryos shall also not be grown for longer than 14 days following fertilisation or the formation of the primitive streak, whichever comes first. It is clear from the regulations given by ICMR, that India has laid prohibitions on research with regards to the implantation of human embryos into human uteruses after any kind of in-vitro modification. The restrictions also forbid human gene therapies with regards to embryos.

Nevertheless, the topic at issue is whether or not the given guidelines are enforceable and what happens if they are broken. Disregarding these guidelines is considered to be an unethical practise and professional misconduct. Since any doctor found guilty of engaging in improper professional behaviour under the Medical Council (Professional conduct, Etiquette and Ethics) Regulations, 2002 may have their licence to practise medicine revoked and be removed from the Medical Council of India's registry, the ICMR rules can therefore be implemented indirectly.

The Delhi High Court further stated in the case of "*Roche Products India Pvt Ltd v. Drugs Controller General of India*[34]*"* it is an unshakable principle that the guidelines are government directives and that the courts may proceed with enforcing the guidelines as legally enforceable rights so long as they serve as an addition to or supplement to the existing law.

It's also essential to note that additional regulations, such as the Drugs and Cosmetics Act, 1940, and the Indian Assisted Reproductive Technology (Regulation) Bill, 2010, could also be relevant to matters concerning designer babies.

Therefore, the major concerns for prohibition of research in this area are that there is unawareness on the the technology's long-term effects and on the misuse of CRIPR technology.

(D) Other countries

[32] National Guidelines for Stem Cell Research, Indian Council of Medical Research and Department of Biotechnology, 2017, clause 8.3.1, https://www.jetir.org/papers/JETIR1908861.pdf.
[33] National Guidelines for Stem Cell Research, Indian Council of Medical Research and Department of Biotechnology, 2017, clause 8.3.2, https://www.jetir.org/papers/JETIR1908861.pdf.
[34] Roche Products India Pvt Ltd v. Drugs Controller General of India, (2015) 63 PTC 423 (India)

 [ISSN 2581-5369]

Under the Assisted Human Reproduction Act of 2004, human germline alteration is forbidden and considered a crime in Canada. Although China does not yet have laws governing genome editing, it does have guidelines known as the "Ethical Principles and Conduct Norms of Human Assisted Reproductive Technologies," which forbid altering a human embryo's genes in order to facilitate procreation. Reproduction is the sole activity that is prohibited; research is not. Research-related experiments that are carried out on embryos that will never mature into humans are allowed since they do not fall within the rules. It has been alleged that Chinese scientists have carried out gene editing studies by taking advantage of this gap.

Parallel to this, Japan does not have any laws governing genome editing. It did, however, offer an interim assessment in April 2016 that accepted the basic study on genome editing to modify genes in fertilised human eggs, but came to the conclusion that it was wrong to put an embryo back into a womb once a faulty gene was fixed by genome editing. According to the LESG study, genome editing research may be carried out to alleviate congenital diseases that are difficult to treat, enhance assisted reproductive technologies, and deepen our understanding of embryonic development. Nevertheless, the report suggested that after the embryos had developed for 14 days, the researchers should destroy the human embryos and stop their work. The committee rejected the practice of human genome editing for medicinal purposes due to the associated dangers.

VII. INTELLECTUAL PROPERTY RIGHTS

The first question that pops up is whether a human gene can be patented in India?

Article 27 of TRIPS Agreement states that “Any product, process which is new, involves an inventive step and has an industrial application shall be patentable”. The list of Certain inventions which are not permitted to get patent rights are as follows:

1. Patents cannot be approved for inventions that run differing to morality, public welfare, or cause harm to humans, animals, plants, or the environment.
2. Discoveries of living organisms or natural substances are excluded from patentability.
3. Plants and animals, (excluding micro-organisms), along with their seeds, varieties, and species, are not eligible for patents.
4. Biological procedures for the creation and propagation of plants and animals are ineligible for patent protection.
5. Processes aimed at treating humans or animals for health benefits or economic gain are not patentable.

 [ISSN 2581-5369]

6. The discovery of a new use or property of a known substance does not qualify for patent status.
7. Methods related to agriculture or horticulture are not considered for patents.
8. Traditional knowledge is not subject to patent protection.

Securing patents for biotech innovations can be a formidable task in India due to ethical considerations and potential perils linked to gene ownership, genetically engineered humans, human cloning, genetic alteration, animal well-being, and environmental consequences. Although biotechnology is highly valued by scientists, it frequently introduces intricate dilemmas, rendering the patent acquisition process in this domain a challenging pursuit in India.

Section 3(c) of the Patents Act, 1970 bars patenting on the findings related to living entities or substances that occur naturally. Hence a naturally occurring isolated gene cannot be secured by patenting, but a genetically modified gene may be eligible for patent consideration if it is both innovative, inventive, and serves an industrial purpose.[35]

A gene patent denotes the exclusive privileges bestowed by an authority upon an individual or organization that asserts to be the initial discoverer of a specific gene sequence. The proprietor of such a patent has the only authority to determine how the gene may be used.

In the case of "*Association for Molecular Pathology v. Myriad Genetics*,"[36] US Supreme Court determined that human genes cannot be subject to patents. The act of isolating a human gene, on its own, does not qualify it for patent protection. The court also drew a distinction between naturally occurring human DNA and DNA that has undergone laboratory manipulation.

A patent cannot be obtained in the European Union based only on the discovery of a human gene's entire or partial sequence, as per European Parliament Directive 98/44/EC. Nonetheless, a technological procedure or an element derived from the human body, such as a DNA sequence, may qualify an invention for patent protection.

The "Guidelines for Examination of Biotechnology Applications for Patent"(Part 11), 2013 in India specify that sequences directly isolated from nature are not eligible for patenting. Furthermore, any innovation with intended use or practical applications that contradict public morality or pose significant risks to humans, animals, or the environment is also not eligible for patent protection.[37]

[35] Sagarika Kapur, Issues related to Patentability of Biotechnological Inventions,LexOrbis,June 1,2020, https://www.lexorbis.com/issues-related-to-patentability-of-biotechnological-inventions/
[36] Association for Molecular Pathology v. Myriad Genetics, 569 U.S. 576 (2013)
[37] Indian Patents Act,1970, No.39,Acts of Parliament, 1970 Section 3(b)

A product or procedure must fulfil certain requirements in India, such as being unique, incorporating an innovative step, and having potential for industrial use, so as to be granted a patent.[38] Simply discovering something, such as a naturally occurring gene, doesn't qualify for patent protection.[39] Therefore, the mere act of discovering a gene found in nature cannot be considered an invention and, therefore, cannot be patented.

The intellectual property rights (IPR) issues associated with designer babies in India are complex and evolving, with numerous unresolved questions regarding the patenting and ownership of gene-edited embryos. The Indian government is taking a cautious approach toward patenting gene editing technologies.

VIII. SUGGESTIONS

The moral value of new technology is not inherent; its ethical implications depend on how people choose to utilize it. With the wide array of possibilities this technology offers, decisions regarding the enhancement of human traits like height, colour, and gender must be made judiciously. If these choices fall into the hands of individuals, it might dilute the fundamental differentiating characteristics of human beings. Throughout history, human nature has demonstrated a penchant for greed. Therefore, when granted the power to manipulate the evolution of humanity, it is practically inevitable that selfish decisions will prevail.

For instance, in India, a society with a prevailing male bias, a significant portion still upholds the belief in the superiority of male offspring, as evident in the alarming rates of female foeticide. If the option to select the gender of a child were available, a majority might opt for male children, exacerbating gender disparities. The wide use of this technology, accessible to a broad populace over a few generations, could lead to a homogenized DNA composition among the majority, diminishing genetic diversity and potentially increasing susceptibility to diseases in the future.

With Reference to the Hindu personal laws, which prohibit Sapinda marriages, highlights the legislative intent to mitigate the risks associated with interrelated gene heredity. Therefore, it is imperative that we exercise caution in the application of this technology and place restrictions to prevent unethical applications.

Although genome editing can serve as a tool for gene therapy, potentially curing life-threatening diseases like cancer and contributing to improved standards of living and life expectancy, it is crucial to address the various concerns surrounding its use. Stringent legislation can be enacted

[38] Indian Patents Act,1970, No.39,Acts of Parliament, 1970 Section 2(1)(j)
[39] Indian Patents Act,1970, No.39,Acts of Parliament, 1970 Section 3(c)

 [ISSN 2581-5369]

to regulate genome editing, involving government approval and strict surveillance. Actions conducted beyond the legal framework can be penalized with severe consequences. The establishment of an international committee comprising accomplished scientists can provide valuable insights for the effective and ethical application of gene technology, ultimately benefiting humanity.

IX. CONCLUSION

As philosophers Savulescu and Kahane have articulated, cherishing children as gifts or blessings doesn't imply passivity in the face of illness or disease. Parents who prioritize their children's health do not perceive themselves as designers, nor do they view their children as products of their will or tools for their ambitions. This distinction becomes evident when considering parents who aspire to bioengineer their child's intellectual or physical abilities.

Thus, it's imperative for parents to accept their children unconditionally, regardless of their inherent traits. Love and affection should not be reliant on physical appearance or IQ levels. Consequently, genetic customization beyond medical necessity is considered unethical.

Germline gene editing undeniably holds vast potential for advancing humanity. However, it is equally evident that this is a sensitive issue demanding careful handling. Given India's current deficiency of a definitive legal framework for regulating the creation of designer babies, there is a pressing need for action in this domain. Therefore, the key to unlocking a brighter future for humanity lies in advancing research on germline gene editing through the development of appropriate laws and regulations.

In conclusion, genome editing has the potential to significantly improve our world by enabling the treatment of life-threatening diseases and disorders. It is a powerful tool in the hands of the scientific and medical community, capable of being a boon to humanity when used ethically. However, If applied without regard for ethics, it also has the ability to undermine the very essence of the human race.

*****

 [ISSN 2581-5369]