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DESIGNER BABIES THROUGH GENETIC ENGINEERING; LEGAL AND ETHICAL CHALLENGES UNDER PATENT LAWS.

AUTHORED BY- UPASANA SAHANI
Research Scholar, School of Law, Christ (Deemed to be University)

Abstract

The beginning of genetic engineering has cleared and facilitate the concept of "designer babies," here the parents of the babies have the option to modify or choose the specific traits for their offspring by the new biotechnological methods. This new technic has raised new significant legal and ethical challenges mainly concerning patent laws and intellectual property rights associated with genetic modifications. The ethical dilemma related to genetic modification starts with the problem of ownership of genetic modification techniques and it is a complicated matter which need a rigorous scrutiny. Patent laws currently lack comprehensive frameworks to regulate the applications of genetic engineering in humans, resulting in ethical thickets that may inhibit access to these medical advancements, especially for underprivileged populations. So, it can be seen that the commodification of human life is raising important moral questions about the nature of parenthood, identity, and social equality. The research also focuses on the moral issue where the gene modification can create a class divide, benefitting the group of people those who can access and afford such facility. These differences could intensify existing socio-economic inequalities in a society where genetic traits become identical with social value, thus prompting concerns of utilitarianism and eugenics. This paper scrutinizes the connection of genetic engineering, patent law, and bioethics, concentrating on whether genetic modifications in embryos can be patented and what are the implications of such patents. By estimating the balance between incentivizing innovation and safeguarding public interest, this research explains that a legislative framework must be established to address the complexities surrounding genetic enhancement, as well as the rights of genetically modified individuals and the responsibilities of those involved in such enhancements. To mitigate abuses and unintended consequences, related to legal, ethical, and scientific problems to direct the complicated landscape of designer babies and genetic engineering.

Keywords: Designer babies, Genetic engineering, CRISPR, Patent law, Ethical challenges

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etc.

INTRODUCTION

Genome editing technologies has great potential for scientific research and society then the other invented technologies, this provides rapid, effective, detailed, and effective tools to alter or modify the content in the cells of any living organism. The use of the genome editing techniques, can have a effect on the cells of the body or on the somatic cells can be modified, treating or curing patients of chronic, lifelong illnesses. The speedy progressions in genetic engineering have created the way for the creation of designer babies, as editing the genome of human embryos to make changes in the unborn child can also repair the germline of human beings, eliminating hereditary diseases in new-born babies leading to various ethical and legal concerns. Genetic engineering can now offer detailed information about an unborn child's genes also known as designer baby refers to the creation of babies who were genetically modified by the genetical engineering, or germline editing. Germline editing is the unique technique that is used for altering the DNA in the cell.[1] This technique allows parents and healthcare providers to make decisions about the child's traits and characteristics where there can be alteration or modification in the embryo to create a specific quality in matter of appearance, intelligence, obedience, gender or even disease immune and a lot more. The germline modification in a designer baby can be created in a way that those babies can be immune from the hereditary diseases like leukaemia, haemophilia, HIV, and other such disorders, But this technology's consequences can beyond the individuals choice, as this can lead to discrimination, privacy violations, and the commodification of human life[2]. This process starts a concern with regard to ethical issue that is eugenics and the potential for creating a genetically "superior" class of humans. And this process will affect the human diversity and the inherent dignity of all individuals, irrespective of their genetics. Additionally, the use of gene editing technique for non-therapeutic purposes, like increasing physical or cognitive abilities, raises concern about the equitable access to these technologies and the potential for socioeconomic disparities.

The legal outline which addresses about the designer babies is also bounded with complexities as it has many challenges. The patenting of the gene editing techniques and the genetic

[1] Contributor, *Designer Babies: An Analysis of Legal And Ethical Considerations »*, (May 2, 2024), https://www.lawaudience.com/designer-babies-an-analysis-of-legal-and-ethical-considerations/ (last visited Mar 15, 2025).
[2] Ibid.

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technologies and the ensuing commercialization of these products and have raised the concerns regarding the availability and affordability of these treatments. In this the CRISPR has a major role in particular it represents a revolutionary progression in genetic engineering. [3]As it allows changes in the protein structure DNA for the purpose of gene editing, and to modify specific needs which are required and have a effect on the disease or other traits. Combined with IVF and PGD, which are traditionally used to select embryos without genetic abnormalities, CRISPR has created the possibilities for not only therapeutic interventions but also the enrichment of human capabilities. And this rising interest in human germline modifications changes to genes that can be passed to future generations and has been associated with various challenges. These modifications have the capacity to give solutions to inherited genetic disorders but also raise complex ethical and societal issues[4]. However, these challenges are very much complex in nature it has a impact on the law making and human rights and to resolve this a new approach that balances the human right along with societal interest.

The designer babies and genetic engineering are regulated emphasizing on the problems, evolving nature of this issue. In this the ownership of genetic modifications raises questions about intellectual property rights and the commercialization of human life [5]and the need for comprehensive policies to govern the use of genetic technologies and protect human rights, While the potential benefits of designer babies are significant, the ethical and legal ramifications necessitate careful consideration and regulation to ensure that advancements in genetic engineering do not compromise fundamental human values. [6]These variations emphasis more on the fact that while the science behind genetic engineering is global, the legal and ethical boundaries are shaped by distinct cultural, political, and societal values.

IMPLICATIONS OF GENE EDITING TECHNOLOGIES AND ETHICAL ISSUES

Researchers must not be careless in using gene editing and stem cell technologies though there is a general understanding of the benefits it might hold in tackling genetic diseases and

[3] Contributor, *Designer Babies: An Analysis of Legal And Ethical Considerations »*, (May 2, 2024), https://www.lawaudience.com/designer-babies-an-analysis-of-legal-and-ethical-considerations/ (last visited Mar 14, 2025).
[4] Christopher Gyngell & Tom Douglas, *The Ethics of Germline Gene Editing*, Journal of Applied Philosophy, https://www.academia.edu/29210545/The_Ethics_of_Germline_Gene_Editing (last visited Mar 15, 2025).
[5] Ibid.
[6] Bartha Maria Knoppers & Erika Kleiderman, *"CRISPR Babies": What Does This Mean for Science and Canada?*, 191 CMAJ E91 (2019), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6342697/ (last visited Mar 15, 2025).

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eradicating them altogether. [7]Such technologies can also help in the better understanding of the human body and why and how certain people are more likely to susceptible to certain diseases. But it must be kept in mind that there are far reaching implications of carelessly using gene editing technologies. Chinese scientist Jiankui He of Southern University of Science and Technology registered a clinical trial where he had implanted genetically modified embryos using the CRISPR Cas9 technology.[8]

He had genetically edited the CCR5 gene relating to HIV/AIDS in the embryos. Two baby girls, namely Lulu and Nana, were born from this clinical trial. He had not received approval to conduct the trial and had taken a gigantic risk without any ethical considerations. Post the investigation of his work, it came to light that the two embryos were edited in different ways. While the process used was the same, the product was different. [9]One of the embryos was said to have lost five proteins due to the editing which could have seriously affected her immunity. The consequences of this were drastic.[10] There is also the possibility of mosaicism. This can lead to a myriad of problems that can be inherited by future generations as well. A few mutated cells in the body can lead to diseases and sometimes, a single cell might develop a tumour and the consequences cannot be treated until the affected cell or cells are destroyed.40 In addition to this, there can be off- target effects of gene editing that can sometimes be missed even after thorough screening.

One of the most important ethical concerns regarding designer babies is the potential for intensifying social inequality. As genetic engineering technologies become available, they may only be accessible to those with the financial means to afford them, thereby creating[11] a division in between those who can improve their future genetically and those who cannot. This difference can be said to be a inequality and create a new group of genetically "enhanced" individuals or persons who are advanced, as they can enjoy certain benefit with respect to health, intelligence, and physical abilities, ensuing in an increasingly stratified society[12] this consist a different kind of complexity, because the primary focuses of genetic engineering

[7] Ibid.
[8] Chinese-University-v.-Controller, https://spicyip.com/wp-content/uploads/2023/10/Chinese-University-v.-Controller.pdf (last visited March 10, 2025).
[9] Supra Note 04.
[10] Supra Note 08.
[11] *Designer Babies: An Ethical Dilemma*, Hadron, IMSA (Nov. 27, 2023), sites.imsa.edu/hadron/2023/11/27/designer-babies-an-ethical-dilemma. (last visited March 10, 2025).
[12] Ibid.

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embryos cannot provide harmony themselves. This raises ethical questions about parental rights and the extent to which parents can make potentially life-altering decisions on behalf of their future children. Critics argue that the inability of embryos to consent creates a moral quandary that must be addressed before proceeding with human genetic modifications[13]. Another ethical issue associated with the option of unplanned consequences which are the outcome of genetic modifications. The long-term effects of altering an individual's genetic makeup are not fully understood, which raises concerns about potential negative health impacts, both for the individual and future generations.

Critics argue that until more research is conducted to comprehend these risks, the use of gene-editing technologies should be approached with caution.[14] Ethical decision-making regarding designer babies also necessitates strict regulation and oversight from governments and international organizations. Different countries currently have varying levels of regulation regarding genetic engineering, creating potential inconsistencies in ethical standards. Striking a balance between fostering innovation and protecting human rights remains a critical challenge as the technology develops, while ensuring that the decision-making process remains informed and inclusive of diverse societal perspectives[15]

The idea of designer babies brings many important and debatable ethical dilemmas that the society must resolve as it will be relatable due to technological advancements in genetic engineering & it continue to evolve. Subjects like social inequality, informed consent, eugenics, unintended consequences, and the enduring impacts on future generations raise more complexity about the morality of editing human embryos. [16]The ethical dilemmas of designer babies demonstrate the complexities that are integral in advancing genetic engineering technology. Thorough careful consideration the future of genetic modifications can be shaped while maintaining human dignity and ethical integrity.

THE INTERSECTION OF GENETICS AND PATENT LAW

The quick advancing genetic engineering technologies like CRISPR/Cas9 have much definition imposed on the whole nature of the biomedical sciences, enabling capabilities that

[13] *Designer Babies: The Ethics of Human Genetic Engineering*, Mirage News (Apr. 24, 2023), https://www.miragenews.com/designer-babies-ethics-of-human-genetic-992678 (last visited March 10, 2025).
[14] *Ibid.*
[15] *Ibid.*
[16] Supra Note 09.

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have not been identified previously, even creating scopes such as the possibility of designer babies' embryos with the genetic traits that are purposely defined. This is a new area fraught with legal issues making the patent realm even more challenging against the prongs of ownership, ethics, and commodification of human biology. Thus, considering that the society is on the verge of a genetic revolution, it is essential to look into the integrated legal framework concerning genetic modifications as well as the ethical issues involved in such intense human life intervention.

The designer babies and the complexity related to it lies the patentability issue-the legal ownership and commercial use of a biotechnical invention. Patent laws have customarily given inventors exclusive rights over an invention that satisfies certain criteria; it must be novel, non-obvious, and useful[17]. Yet, the ever-challenging life sciences place increasing strain on these fundamental principles which witness the very question of whether genes themselves-the basic building blocks of life-should be patentable. In a landmark judgement in the case of Association for Molecular Pathology v. Myriad Genetics[18], the Supreme Court held that patentability could not extend to human genes occurring naturally and hence unmodified remains in the public domain. This decision seems to resonate with the point made in patent law that human life should not be commodified, a point that continues to trickle down and influence the discussing relating to designer babies[19]. On the other hand, notwithstanding these decisions, implicating patent law, biotech firms and academia continue to act and maintain ownership and commercialization rights on genetic engineering technologies. This ambiguity fosters a landscape where the pursuit of profit may supersede ethical considerations, leading to what some critics refer to as "biopiracy," the commodification of human genetic material for financial gain.[20]

In India patent regime, governed by the Indian Patent Act, 1970, aligns with global standards of novelty, inventive step, and industrial applicability and for the designer babies and gene editing the patent acts is applied. The Act introduces additional exclusions under Sections 3 and 4[21], reflecting India's socio-economic and ethical priorities, as in Section 3(c) [22]Excludes

[17] Supra Note 01.
[18] Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 576 (2013)
[19] Assoc. for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 576 (2013), Justia Law, https://supreme.justia.com/cases/federal/us/569/576/ (last visited March 10, 2025).
[20] Supra Note 01.
[21] The Indian Patent Act, 1970, Sections 3 and Section 4.
[22] The Indian Patent Act, 1970, Sections 3(c).

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the patentability of "the mere discovery of a scientific principle or the formulation of an abstract theory.", Section 3(j)[23]: Prohibits patents on "plants and animals in whole or any part thereof" and "essentially biological processes.", Section 3(b)[24]: Disallows inventions if their primary use could harm public order, morality, or human, animal, or environmental life. These provisions, particularly Sections 3(c) and 3(j)[25], pose significant barriers to patenting gene-editing technologies in India which has a direct relation with designer babies. Unlike the U.S. and Europe, where patents can be granted on genetic materials and editing tools, India prioritizes public interest and the prevention of biopiracy. While global standards prioritize innovation and commercialization, India's framework reflects its developmental concerns, emphasizing accessibility, public morality, and protection of biodiversity.[26] The stricter exclusions in India ensure that gene-editing technologies remain accessible but may discourage foreign investment and limit innovation within the country. The divergence in patentability criteria underscores the need for a balanced approach that harmonizes global standards with local ethical and economic priorities, particularly in the case of transformative technologies like gene editing.

EDITING OF HUMAN GENES

There is a lot of debate surrounding the recent discovery of the CRISPR/CAS9, which works for the gene alteration. These changes can be introduced to both a normal form of gene and mutant gene. CRISPR/CAS9 is covered by several patentees in various fields following multiple patents. The first human edited infants were created in China when Dr. He cut away an HIV gene from human embryos, sparking a global moral outrage. Dr. He facing criminal charges by the Chinese authorities. [27] for the same so it can be clearly understood that editing of human genes is only a scientific challenge to deal with but also a legal issue.

From an evolutionary point of view, natural selection and other processes cannot significantly reduce the frequency of disease associated gene expression in humans, especially within a brief period of time. Genetic engineering plays a important part in this situation. Scientists can boost a baby's resilience to a number of inherited disorders, including breast cancer and cystic fibrosis, by changing the embryo's DNA etc. The issue therefore starts from the fact that

[23] The Indian Patent Act, 1970, Section 3(j).
[24] The Indian Patent Act, 1970, Sections 3(b).
[25] The Indian Patent Act, 1970, Sections 3(c) and Section 3(j).
[26] Supra Note 11.
[27] Supra Note 01.

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scientists try to improve the DNA of infants by altering germline cells rather than somatic cells. Only that person will see a change in gene expression when changes are done to their somatic cells. But since germline cells are reproductive cells, any alterations made to them will be inherited by subsequent generations. Thus, it is possible to reduce the frequency of hereditary illness expression in subsequent generations by genetically altering germline cells in embryos. Even while this seems to have a lot of potential advantages, there are drawbacks that need to be taken into account for the good of society.

The possible advantages of genetically altering embryos are currently being balanced against the potential drawbacks for society. In order to aid those who suffer from severe genetic abnormalities, research on designer babies is being conducted "to avoid their having heritable diseases coded by mutations in DNA". [28]However, the growth in designer babies actually disproportionately affects people with severe genetic diseases since their sickness often prevents them from achieving socio-economic stability, making it impossible for them to afford the high cost of genetic alteration.[29] The expenses of genetic manipulation are currently very high, even though gene editing will undoubtedly become less expensive as genetic technology advances. Therefore, promoting genetic modification procedures will result in a limited consumer base that includes only those who can afford gene editing. This will make it more likely that those who don't need these resources will take advantage of them, creating a social divide between those who can afford gene editing and those who can't.

While those who more urgently need gene editing to prevent heritable diseases might not be a ble to afford it, consumers who can afford it might attempt to alter their child's genome to inc rease the likelihood that they will be tall or have particular colored eyes, both of which can be considered resource abuse. Although there are many potential advantages to designer babies in terms of preventing sickness, it is important to take into account the moral conundrum that separates the exploitation of gene editing resources from their use for ethical and sustainable purposes. [30]It's also critical to assess the strategies being used by scientists to develop designer offspring. The issue of whether gene editing should be restricted to a person is brought up because altering germline cells in embryos can have an impact on entire generations. Enhancing a baby's DNA can improve its health potential, but the science of gene editing isn't independent

[28] Supra Note 07
[29] Supra Note 05.
[30] Designer Babies: An Ethical Dilemma – Hadron, (Nov. 27, 2023), https://sites.imsa.edu/hadron/2023/11/27/designer-babies-an-ethical-dilemma/ (last visited Mar 15, 2025).

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of individuals who can and will misuse it. Society must, therefore, decide whether or not to allow the development of designer babies by weighing the potential benefits and drawbacks.[31]

CONCLUSION

Designer babies are challenged with different legal issues raised by genetic engineering technologies increasingly advancing, and these will be worthy of careful examinations in many perspectives. For patent law, it should continue developing in defining particular ownership and ethical usefulness rules of genetic inventions within the balancing act of innovation against the protection of human rights. Ethical matters should also focus on the broader social context, informed consent for genetic alteration, and the potential differences in status between enhanced and non-enhanced individuals. Ethical legalistic & theological consensus needs to be reached on the issues by which the society will come face to face with the reality of designer babies.

There can be establishment of a responsible framework accommodating scope for genetic engineering within the areas of pain-protection life and dignity of every person unless there is constructive deliberation among legal experts, ethicists, scientists, and the public. It is under patents where designer babies, conceived in the womb of gene engineering, stir up tremendous rights and responsibilities. Emerging technologies such as CRISPR-Cas9 facilitating accurate germline gene editing make the question of embryo manipulation even more complicated. This introduction deals with the issues of crossover between gene engineering, ethics, and law on the issue of designer babies requiring responsible governance in the rapidly evolving field. Though it foresees significant benefits from designer babies for individuals and societies, most especially the elimination of genetic diseases, the ethical and legal complexities need very careful consideration and a strong regulatory framework within which to venture into this territory.

[31] Supra note 08.