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Original Article

Beyond The Blueprint: Are Designer Babies Patentable in India?

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Abstract - *Over the last decade, innovations have increased, and the importance of the human healthcare field has also grown. Recently, the University of California and the Broad Institute began battling over the patents related to CRISPR CAS - genome editing. CRISPR CAS9, or Clustered Regularly Interspaced Short Palindromic Repeats, is a kind of precise molecular scissor that scientists use to edit faulty genes. Gene editing has its pros and cons. On the one hand, it is accepted that gene editing resolves children's health issues and provides security to future generations. However, on the other hand, it becomes crucial when it is used to design babies. The natural birth process of human life is being tampered with for selfish motives. Moreover, what would the impact of the altered genes be on the next generation? It may pose a threat to humanity. Every family may not be able to afford a beautifully designed baby. It may also raise questions on the constitutional validity of the practice. Has nature transferred the app to design babies into human hands? Intellectual Property Rights (IPR), protection for designing babies, raises a number of difficult technical and ethical-legal issues. Designing of babies is still developing and needs to be regulated. China, the US and India have used the technology successfully. There is a need to interpret the concept of designer babies through the lens of the Patents Act 1970. The paper proposes to draw the boundaries for the issues related to designer babies.*

Keywords - *Biotechnology, Gene editing, Designer babies, CRISPR technology, Gene patenting.*

1. Introduction

The title of this paper brings a question in the technological age as to how far one can design one's own baby. Is that legally possible? If so, how much design is acceptable? This topic creates a platform for inventors to think, create and obtain patents for genetically modified or designed babies. The subject of patenting of 'Life Forms' has been drawing a great deal of attention all over the world. An old decision of *Diamond v. Chakrabarty,* [1980] 447 U.S.303., led to the opening of several developments in gene patenting and biotechnological inventions. In the above case Ananda Mohan Chakrabarty had developed a genetically modified bacteria which was prohibited from patent grant. Later, it was successful and created a history in gene patenting. In the ruling of the above case, the statement was made to incorporate genetically modified bacteria patentable. In the present situation, genome editing is gaining momentum. The genome is the entire sequence of DNA of an organism. The genome includes genes. Gene is an important element in the human body and is responsible for a lot of aspects that take care of the human body. It is found that certain diseases and disorders are genetic in nature. The personality of a person also depends upon the genes. There is gene augmentation or gene therapy which is not similar to gene editing. A new gene is introduced to rectify the defective gene in the first process. In the second process, there is alteration or modification of the DNA. Innovations have moved to such an extent that there is a possibility of replacing natural human beings with extra smart and attractive humans created by modifying the genes where the end-product is genetically engineered babies or designer babies. Hence a baby could be created with genes free from autism, Parkinson's and other diseases. One can design a baby with new hair colour, eye colour, height and structure, active in sports or studies, etc. Gene editing is a method used to modify the DNA in a cell. Genome editing is the process where the DNA is modified, either by altering, removing or adding nucleotides to the genome. It is not restricted alone to humans but could also be used in animals or any other organism. Gene editing technology today with CRISPR/ CAS 9 is growing fast. The technology Clustered Regularly Interspaced Short Palindromic Repeats. CAS9 means CRISPR-associated protein, which cuts the DNA at the target site. It is widely used as it is of low cost and simple to use. This process is adopted by obtaining the parents' consent and following the scientist's guidelines. The consent of the person not born does not arise when it is being designed. However, later, there may be issues when the designed human raises a concern as he or she is not made naturally but is designed to be superhuman, which they do not want to be. There are many ways in which genetically engineered babies

are created, maybe by germline engineering or preimplantation genetic diagnosis. Germline engineering is genetic alteration within the germinal cells or the reproductive cells such as oocyte and spermatogonium. Preimplantation genetic diagnosis is genetic profiling of the embryos before implantation or in oocyte before fertilisation. This process is also used to identify genetic diseases. However, the design of babies is not a novel concept; it began in 1989. In the year 2000, Adam Nash was born in the US to cure the ailment of his elder sister. Molly Nash was born with a genetic disorder where her body could not produce healthy bone marrow. Hence, a genetically engineered baby was created to use blood from his umbilical cord. In the UK in 2003, the Designer Baby was created for a similar purpose. A genetically engineered baby named James Whitaker was created to help his ailing brother. The UK government had opposed the procedure because it was felt that it was unlawful and unethical, but they went ahead with it. The process was adopted in the US.

The world's first designer baby created with the DNA of three parents was born in Mexico in 2016 [1]. China also developed designer babies with the intent to cure diseases. India is still in the process of development. The entire purpose with which the innovation had been brought into existence was to cure diseases or rectify a disorder. It is ethical and well-accepted until the medical purpose of designing babies is considered. However, once the shift changes to fanciful approaches, it becomes difficult to justify the process. With the designing of babies, it appears that nature has transferred the application (app) to design babies into human hands. It is worth appreciating that science has developed to incorporate such innovations. When such innovations are promoted, there is a need to analyse all possible issues in continuing with such practices.

When the origin of gene editing was investigated, it was seen that in 1973, the first organism genetically engineered for antibiotic resistance was created. The bacterium E. coli created by Herb Boyer and Stanley Cohen gives a new dimension to the world of genetics. Then, in 1982, synthetic insulin was developed as a part of genetic engineering. So, for the betterment of human health, developing therapeutic practices and reducing diseases were the motives of genetic engineering. Research flourishes further with Monsanto, genetically modified crops and in 2003, "selfish gene" being researched upon. (It is a theory where cells and organisms exist simply as packages to protect and transmit genes.) In 2012, the University of California-Berkeley and the Broad Institute of Harvard University independently discovered that CRISPR/ CAS9- a bacterial immune system can be adapted to serve as a gene-editing tool [2]. The use of CRISPR/ CAS9 led to the conflict between patent claimants. The University of California, Berkeley and the Broad Institute began battling over the patents related to CRISPR/ CAS9. In 2016, the USPTO granted patents first to Broad Institute even though the University of California was the first to apply for patents.

The Broad Institute got its patent application processed fast by paying extra fees. The University of California initiated an interference proceeding to check if the claims were the same in the patent application. The University of California had not specifically mentioned the exact use of CRISPR/CAS9 on eukaryotic cells in its patent application. The patent dispute was settled in favour of Broad Institute in 2017. The USPTO judged that in 2012, the patent application only claimed the process of gene-editing with CRISPR on prokaryotes such as bacteria. Meanwhile, the Broad Institute had a limited scope of using CRISPR/CAS9 technology on eukaryotes such as plants and animals. Hence, anyone wanting to adapt CRISPR/CAS9 technology would have to obtain a license from both parties, as one holds a patent with a wider ambit and the other with plants and animals [3]. In 2021, the WHO came up with a report stating the need for somatic, germline, and heritable gene editing that would follow the public health order of safety and ethics.

2. Jurisprudential Perspective of Gene Patenting

Babies are designed and produced by genome editing. The technology to edit the gene demands intellectual property protection. There is a need to analyse the jurisprudential base of designing babies with an intellectual property lens. If Lockean theory is applied, designing babies is a part of one's labour and hence his property. Creativity is the component that needs to be protected and is the base of arguments where intellectual property protection is warranted. Creativity in the world outside is well accepted. When the jurisprudential aspect of intellectual property is looked upon, many justifications are provided for the need for protection. The theories of justification are extended to all kinds of tangible and intangible property. The same features that apply to tangible property are extended to intangible property like sale, lease, gift and all other types of transfer. Hence, taking the Lockean theory of property, the innovative genome editing process fits into intellectual property protection.

The Hegelian justification of property is that property is an integral part of one's personality. The core aspects of one's life, like liberty, identity and privacy, are extended to property. When a person owns a tangible property, he fights for the security, ownership, freedom and enjoyment of the property. It is a right in rem and, therefore, is a valuable asset that becomes a part of his personality. Now, when intangible property is considered, the same features that form the core values, such as privacy, liberty, and identity, are extended, and it is justified that intangible property needs protection as it is part of the creator's personality. This personality theory of justification can be extended to genome editing. The creator's efforts regarding DNA editing skills are appreciated, and it authorises intellectual property protection. However, when the other side of the personality is being edited without the person's consent, it becomes an issue and hence needs proper regulation.

When utilitarian theory is taken to protect designer babies, the element of public good is considered. The public good of this particular property is only with respect to curing ailments or correcting some genetic issues and not with the fancy design features being adopted. Suppose Hohfeld's analysis of rights and duty is considered to be the protection of intellectual property. In that case, it is justified as it becomes the state's duty to protect the creator's rights. Since every right cannot be protected for reasons like national security, environmental protection, and other moral issues, the state has incorporated limitations to protection through legislation. The limitations are put through S.3 of the Indian Patents Act 1970.

Three theories could be developed by taking into consideration the purpose of designer babies.

- The first theory is an ineliminable theory, where either the medical conditions of the parents prohibit or lead to medical problems in conceiving a child naturally or due to the genetic disorder of the sibling, a genetically engineered baby is created. So, the ineliminable theory focuses on the need created by nature to produce a baby through the use of technology, which is justified.
- The second theory is that of contentment and recreation. Due to the sound financial background of the parents, they have the leisure to make choices about modifying the baby's DNA. The choices may vary from a disease-free baby to creating a baby according to one's creative and imaginary ideas. It is with the second theory is that regulation becomes important.
- The third theory is of forced acceptance. The present generation may knowingly or unknowingly shape the characteristics of the future generation, which may not be acceptable to the future generation. This may lead them to live in compulsion with the traits developed artificially. This theory of gene editing needs regulation.

3. An Analysis of the Designer Babies through S.3 of the Indian Patents Act, 1970

There are various grounds provided for inventions that are not patentable. When genome editing is concerned, there is a need to analyse various provisions provided under the Act. Hence, when the analysis is done, S.3 (a) refers to inventions against well-established natural laws. Genes are natural; hence, genome editing, where human or animal genes are tampered with through various technological innovations, cannot claim protection. S.3(b) specifies that creativity through inventions is not encouraged for protection where its use or commercial exploitation affects public order or the core moral values or inventions affecting humans, animals, plants or the environment. Gene editing cannot be encouraged as it clearly falls within S.3(b). Further, S.3(c) differentiates between discovery and inventions. All that is discovered cannot be protected. Genes are naturally present. Hence, it cannot be per se. When this argument is raised, it is accepted that it is not the gene calling for protection but the editing of the gene, which is not natural and is created so it needs protection. S.3 (i) explains that any process used to cure diseases and defects or efficiency in humans or animals cannot be protected. Gene editing, when carried out to cure diseases or defects in humans or animals, cannot be monopolised. However, when it is used to design one's own baby, the concept shifts from curing and treatment to one's desires and fancies. So, the question arises of whether it falls under the provisions of non-patentable inventions. S.3(j) stresses that plants or animals in whole or any part of them cannot be patented as they naturally occur. Therefore, genes cannot be protected per se, but the technology used for gene editing can qualify for patents. S. 3(k), as gene editing is done through a computer, the program or algorithm can also be granted to a certain extent as it will come under a computer program *per se*.

4. The Advantages and Disadvantages of Gene Editing

If the advantages are analysed, it is mainly argued that:

- This would lead to a disease-free society. The majority of the genetic diseases would be in control or completely eroded. Hence, people would have a better life and a longer one too.
- The society would be blessed with a variety of performers. The skills of the future generation would be in the hands of the present generation. So, society will witness skilled musicians, dancers, artists, authors, intellectuals with high efficiency, etc.
- This will lead to further growth of science and technology.

When the disadvantages are analysed:

- Only economically sound families can afford or think about gene editing. It would certainly be highly-priced since it is patentable and not so common technology. So, in short, the rich class of society can afford a healthy and longer life. The disparity on the grounds of the class system becomes stronger.
- The naturally talented born humans will face many challenges with competition from genetically engineered humans.
- The consent of the genetically engineered human cannot be obtained before modifying the genes. The human personally may not be contended with the modification. Like for example, when a blue-eyed female is designed and brought up, there are chances that she may develop a taste for natural black eyes. When she understands the truth that she was designed that way, she may not accept it, but she will have no other option.
- At present, we are on testing grounds, and we predict that genetically engineered babies will live better. Only time can prove if our predictions are correct. In the future, the modification may lead to new problems.
- This process will help the rich class of society to genetically engineer the sex of the embryo. Indirectly

contributing to the prohibited norms of the society. (In India, it is prohibited to know the gender of the embryo) If Gene editing is encouraged and not regulated, then it may lead to sex selection by parents.

5. Constitutional Validity for Genetically Engineered Babies in India

Editing the gene may lead to challenges to the constitutional validity of the process in future, where the designed babies will have better physical features than the natural-born babies. Therefore, a distinction arises between the natural-born babies and the designed babies. The other part of the challenge would be the problem where economically sound families can think about the designed babies, and the economically unsound families may not be able to cope with it. The disparity arises in the economic and physical aspects of designer babies. If a proper regulation is not drafted, then inequality will result between babies and parents. This will further lead to the strengthening of certain sociological problems like racism, class-based violence, etc. These challenges can be addressed with a regulation that clearly balances the disparity issues. The regulation should specify that there would not be any difference between genetically engineered babies and normal babies. Only the embryo's origin has been modified; otherwise, the baby is normal. This regulation will be a disclaimer for future issues raised about disparities and the need for extra benefits by either side of the group.

6. International Perspective of Regulatory Bodies

There is a need to relook into the ethical aspects of genetically engineered babies because innovations shift from need-based patterns to dreadful patterns. There is confusion about the destruction that the invention will create in the future. A comparative analysis will help to decide and strengthen the regulatory mechanisms needed. If the US approach to the ethical issues of designer babies is looked into, they began with the invention without a second thought about the consequences. Some doctors fear modifying genes as it is going against nature, but it is justified as curing diseases, which is also a way of going against nature. For others, it is the normal surgical process.[4] There is no regulatory framework to govern the gene editing process. However, as of now, the process is monitored by scientists, the Food and Drug Administration, Centres for Medicare and Medicaid Services, and the Federal Trade Commission.[5] Some advisory bodies, like the Recombinant DNA Advisory Committee, review clinical trials and monitor the norms to be followed[6]. Animals (Scientific Procedures) Act 1986 governs gene editing among animals in the UK. In 2015, the mitochondrial donation was upheld for IVF babies. It helps prevent serious disorders from being transmitted from the mother to the baby, where the healthy mitochondria are donated by a healthy woman and implanted into the baby's cells. When the ethical part of designer babies in the UK was considered, they created a board, the Human Fertilisation and Embryology Authority (HFEA), where every kind of research on human embryos is not entertained, and it is essential to obtain a license from the authority. There are prohibitions laid down, such as:

- Any kind of development beyond 14 days of human embryos outside the human body is prohibited.
- In any way, a genetically altered embryo cannot be implanted into the womb. Except for the mitochondrial donation, as mentioned above [7].

Hence, in the UK, gene editing is monitored and allowed only for curing and treating certain disorders, like improving the genome to reduce miscarriages, but not for any other purpose. From the year 2000, China conducted a lot of research in gene editing and was successful by 2015. China has taken the lead in gene editing by successfully genetically engineered various animals and organisms. The laws in China are very clear and prohibit any kind of meddling with human egg plasma or genes. But still, the research was permitted because the researched egg was not to be used for further development. The restriction imposed by their regulators hinders their research, but gene editing is still being used without the permission of the national regulators. The medical board is reviewing it.[8] Like in the US, the State Food and Drug Administration regulates gene therapy. CFDA will also regulate human somatic cell genome editing. Besides CFDA, the Health and Family Planning Commission (HFPC) will play an active role in genome editing, as they are presently regulating IVF clinics.

There would be an active involvement of consultations from departments like the Ministry of Science and Technology, the Chinese Academy of Sciences, the Chinese Academy of Medical Sciences, and the Chinese Academy of Engineering to provide regulatory mechanisms.[9] A lot of developments in gene editing research have affected Korea, too. Where in Korea, the impact of these developments was assessed through a programme called "Technology Impact Assessment". Korean Biosafety and Bioethics Act does not directly regulate the process of gene editing. There is a provision under Art 47 on Gene Therapy. This provision provides for the regulation of research on gene therapy among humans. Gene therapy incorporates the procedure of gene alteration and the transfer of genetic material.

Though the Bio Act 2016 tries to ban gene therapy on human embryos, there are no clear guidelines as to complete regulation on genetically engineered babies.[10] One of the strictest nations concerning gene editing is Australia. The Prohibition of Human Cloning Act 2002 in Australia provides for 15 years imprisonment for any kind of gene alteration. The government encourages research in genetic engineering. Certain strict conditions are laid along with it, like the embryo after alteration, which should not be placed in the woman's womb. The consent of the parents has to be obtained, and the embryo must be destroyed within 14 days of development.[11]

Since there is a lot of development taking place through CRISPR technology, there is a chance that this law will become more flexible. Concerning plants and animals, there is a change.

Research on human embryos is accepted in Japan. The research on gene editing was successful but was refused from clinical trials, considering the harmful effect on future generations. The debate on ethical issues of genome editing is a matter of concern. To date, there is no proper regulatory mechanism. Developments in gene therapy exist but not in genome editing. European Medicines Agency (EMA) takes care of the human and animal medicines in the European Union. The EMA constituted a committee named the Committee for Advanced Therapies to monitor and regulate medicines made from genes. Clinical trials with respect to genes are out of the jurisdiction of EMA.

Hence, the EU Directive on Clinical Trials was made. This directive and the Food and Drug Administration require every member state to adopt strict supervisory mechanisms based on international regulations. In India, human gene editing is regulated by the guidelines issued by the Indian Council of Medical Research (ICMR), the National Guidelines for Biomedical and Health involving human participants and The National Guidelines for Stem Cell Research. These are mere guidelines, whereas efficiency can only be achieved through proper statutory regulation compared to the guidelines. Germline gene editing is banned in India. As suggested by the Takshashila Foundation, a three-tier monitoring mechanism should be established at the laboratory, clinical trial, and public levels [12].

There is a need for a regulatory body at the international level to provide guidelines to all nations' signatories of the regulation. To draft a law according to such guidelines. Taking the gravity of the effect of the innovation in future, the US National Academy of Sciences, the US National Academy of Medicine, the Chinese Academy of Sciences and Britain's Royal Society organised an international summit on human gene editing in Washington held on December 1 to 3, 2015 [13].

The second three-day international summit on genetic engineering was organised by the Academy of Sciences of Hong Kong, the Royal Society of London, the US National Academy of Sciences, and the US National Academy of Medicine in Nov 2018. In both these summits, expressed different groups showed concerns towards gene enhancement. The problems of social inequalities or other manipulations that would take place were discussed. The need for a regulatory mechanism was also highlighted [14].

7. Conclusion

The paper's title uses the statement used in the US case, which appropriately applies here, as the innovative concept of designer babies can be patented as it falls within all the protection criteria. The problem arises with the tinkering of genes, and the entire natural development process of the baby is modified according to human desire. In future, there are possibilities that the designed humans may ask for separate rights or special treatment as they fall into the minority group. Appropriate regulation is needed to regulate the functioning of designing babies or gene editing.

Hence, anything under the sun made by man can be patented, but when it affects the natural process, a kind of regulatory control is needed. However, there is still a long way to go towards genetically engineered babies, as small genetic mutations can help to design the baby. However, it will be a hefty task to make characteristic changes like height, weight, etc. As for a change in the height of a human, there would be a need for somewhere around 93000 gene variations, which is a difficult task. Genetic enhancement is still being researched [15]. Nothing remains impossible in future. So, as a precautionary measure, it would be good if we could equip ourselves with the proper regulatory framework. A complete ban on the process would not be an ideal solution. Only time will reveal if the technology of CRISPR is a bane or a boon if designing babies becomes a common practice. Let there be a ray of hope through regulations so it doesn't amount to mass destruction. By providing patents for such innovations, there is a need to relook at whether the state is ethically on the right path.

Suggestions

1) Gene editing should be strictly monitored by the state's governing mechanism.
2) At the international level there is a need for a convention based on the issues of gene editing. At least WIPO should develop a mechanism to regulate patents to gene editing.
3) At the national level, the ICMR has already taken steps to issue guidelines in India. This should be supported by strong statutory legislation and monitoring mechanisms by scientists, lawyers, and doctors.
4) Amendments to the current Patent Law in India are needed. If S.3 is interpreted strictly, gene editing does not qualify for patents.

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