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'HI, CAN I HAVE ONE CUSTOMIZED BABY PLEASE? THANK YOU': CRITICAL ANALYSIS OF THE PATENTABILITY OF DESIGNER BABIES IN INDIAN CONTEXT

Kanishk Tiwari[1]

Abstract

The intersection of Intellectual Property Rights with emerging genetic engineering technologies presents unique challenges, particularly in the context of patenting designer babies. This research aims to critically examines the patentability of genetic modifications in embryos under Indian law. The concept of designer babies, where genetic modifications are made to embryos to enhance desirable traits, has sparked intense ethical and legal debates worldwide. The Indian Patents Act, 1970, which permits the patenting of inventions that are novel, involve an inventive step, and have industrial applicability, provides the legal framework for such evaluations. However, Section 3(b) of the Act explicitly prohibits patents for inventions contrary to public order or morality. This paper delves into the ethical considerations and legal constraints surrounding the patenting of designer babies, comparing Indian laws with those of other jurisdictions. By analysing the possible interpretations of the Indian Patents Act, the paper seeks to determine if patents for designer babies could be granted at all and whether they should be allowed. The study concludes with recommendations for amending the current patent laws to accommodate technological advancements while addressing ethical concerns.

***Keywords**:* Designer Babies; Germline Engineering; CRISPR; Patentability; Morality

Introduction

The Intellectual Property Rights basis its foundation on harmonizing the two conflicting ideas of firstly catering to Public Interest, and Secondly, to give due regard to the Interest of the Intellectual Property creator in order to maximize the incentivisation but these objectives are made subject to various ethical consideration enumerated in different statutes.[2] The concept of designer babies, where genetic modifications are made to embryos to enhance desirable traits, has sparked intense ethical and legal debates worldwide.

[1] 5th yr. B.A.LL. B (Hons.) | Maharashtra National Law University, Nagpur
[2] V.K Ahuja, *Law Relating to Intellectual Property Rights* 8 (LexisNexis, 3rd edn., 2017).

Advancements in genetic engineering technologies have brought the concept of designer babies closer to reality, raising significant questions about their patentability and the ethical implications involved. In India, the patentability of genetic modifications falls under the Patents Act, 1970, which allows for the patenting of inventions that are new, involve an inventive step, and are capable of industrial application. However, Section 3(b) of the Act prohibits the grant of patents for inventions contrary to public order or morality.

The author of the paper would attempt to draw parallels to this newly evolving area of jurisprudence with other jurisdictions and move forward to analyze the possible interpretation of Indian Patent Act 1970 to see if such patent can be granted and should (if at all) such patent should be permitted to be granted. The approach adopted by the author for analysis would be critical in nature, concluding the paper with suggestions of amending the current patent law to conform to accommodate the upcoming technological advancements.

Designing the Genes (of Babies)

The developing technologies in the medical field have brought to reality the cures for diseases which were earlier considered unimaginable. It is the Fourth Industrial Revolution (hereinafter 4IR) which is currently enabling a new digital economy, Internet 3.0 and the Programmable Economy.[3] 4IR as a concept was propounded by World Economic Forum founder and chairman *Klaus Schwab*.[4] It contemplates a revolution that 'creates a world in which physical, virtual and *biological systems* of manufacturing that cooperate with each other in a flexible way at the global level.' The interlinked technological advancements under this new 4IR *inter-alia* are Blockchain, big data, biotechnology, artificial intelligence (AI), robotics, Internet of Things (IoT), 3D/4D printing etc.

There are several technologies that are developed pertaining to editing the genetics of humans primarily to cure any genetic defects and secure a healthier life for the unborn human baby. However, ethical considerations have arisen with respect to usage of such technologies for ulterior motives giving rise to question of morality which shall be discussed at a later section in this paper.

Meaning of Genes

Genes are defined as "the medium through which living organisms transmit genetic information from one generation to next. It is our genetic code that makes us the unique individuals that we

[3] WIPO, "Blockchain technologies and IP ecosystems: A WIPO white paper" 11 (WIPO REFERENCE NO. RN2022-2E 1, 2022).
[4] Klaus Schwab, *The Fourth Industrial Revolution* 23 (Portfolio Penguin, 1st edn., 2016).

are." The double helical structure of DNA, initially admired for its intellectual simplicity, today represents to many a double-edged sword that can be used for evil as well as good.[5] Since 1980 after the grant of first patent for living organisms by USPTO in *Diamond v. Chakrabarty*[6] the subject of patents has moved from human-made bacterial microorganisms to human cells to human genes today.

The basic building blocks of life in every living being are genes. Every gene is a segment of deoxyribonucleic acid (DNA), which carries instructions necessary for the growth and functioning of living organisms. It is the Genes that dictate certain characteristics like eye colour (green or brown) and stature (tall or short). Then, those genes work as instructions for making functional molecules like proteins and ribonucleic acid (RNA), which carry out the chemical processes that give life to our bodies.

As discussed, modifying or making changes in the basic building blocks of a living organism has a revolutionary effect, and has been made possible with the advancement in technologies. We shall now briefly discuss first the germ line engineering, then subsequently the most prominent germ line-based gene editing technology that has made such scientific work possible.

For the purpose of this research paper, the identified most successful *germline gene editing*[7] technology, also considered as revolutionary, and relevant for discussion in the present subject matter is CRISPR-CAS9 Technology, the salient features and why exactly that such a medicinal wonder became a bone of contention in medical field shall be discussed.

Germline Engineering (Gene Therapy)

Unbeknownst to most, human genetic engineering has existed for a much longer. Gene therapy is a recent contribution to the field of genetic engineering. The main goal of gene therapy is to alter a patient's gene expression by introducing desired genetic material into body. Treating, curing, or eventually preventing a disease or disability is the goal of these alterations.

There are two main strategies in gene therapy:

1. Gene addition

[5] Pariksha Parmar and Munnazzar Ahmed, "Gene Patenting Rights: A Critical Analysis", in S. Sivaramakrishnan *et.al.* (eds.) *Advances In Biotechnology And Patenting* 205, 206 (Elsevier, 2014).

[6] 447 U.S. 303 (1980).

[7] Germline gene editing is the editing of genes in these reproductive cells or early stage embryos. The reason for the controversial nature of germline gene editing is that, the editing or alteration that has been made, will be passed down and inherited, which raises the concern of ethics, morale as well as safety.

2. Removal of a harmful gene by antisense nucleoid or ribozymes[8]

Essentially, it is well understood that whatever may be the strategy of genetic intervention, it is distinguished on the basis of the type of cell targeted. *Gene therapy can be targeted either to* somatic (body) *cells or* germ (egg or sperm) *cells*.

Somatic gene therapy is the process of introducing a new gene into a growing or already born human with the goal of treating or preventing an existing disease or problem. By altering the receiving patient's DNA through somatic gene engineering, his condition is improved, but the alteration is not passed down to the next generation (no inheritance). However, the latter gene targeting method i.e., germ based which is the second type of gene therapy involves alterations and modifications of DNA in a zygote, the first cell formed from joining of sperm and egg. Crucially, the goal of germ-line gene therapy is to alter the parents' cells in order to pass on changes to the offspring (Inheritance possible).
A distinction at this point is important to be noted, between the terms 'therapy' and 'enhancement' where the former refers to curing or preventing a medically unacceptable condition, whereas the latter is directed to enhance a function on property of the human body.[9]

The germ-based gene therapy/enhancement is what we are concerned with for the purpose of discussion. Hence, it is pertinent now to analyze the working (in brief) of the most prominently used germ-line gene therapy/enhancement technology in usage across the developed nations i.e., CRISPR-Cas9.

CRISPR Technology Functionality

CRISPR refers to "Clustered Regulatory Interspaced Short Palindromic Repeats, that are a critical component of an individual's defence system against bacteria."[10] In other words, CRISPR contain "sequences of genetic code," which include interim sequences known as spacer sequences, which code for past bacterial invaders in the body. These spacer sequences help "the cell detect and destroy [past bacterial] invaders" upon their return, with CRISPR acting as a guide to specific sequence of DNA. Cas9, "a CRISPR-associated protein... that is programmed by small [ribonucleic acids] to cleave DNA," commences the actual gene editing. It binds to the sequence of DNA of interest "and cuts it, shutting the targeted gene off."

Scientists are able to program these sequences so precisely that commentators have likened the

[8] Richard C. Mulligan, "The Basic Science of Gene Therapy" 260 *SCIENCE* 926, 930 (1993).
[9] Archisha Satyarthi, "Dissertation on Patentability of Biotechnology" *UNIVERSITY SCHOOL OF LAW & LEGAL STUDIES GGSIPU* 29 (2020).
[10] *See Id*. at 23.

technology “to a word processor, capable of effortlessly editing a gene down to the level of a single letter.” CRISPR can find the right sequence even when searching through billions of DNA pairs and can do so extremely accurately.

Further, the Cas9 editing process is believed to have three different checks to ensure the correct gene is cut out. First is the precursory scan, which allows Cas9 to locate the appropriate gene. The second check corrects possible errors from Cas9 binding to incorrect genes. The Cas9 protein binds on to the DNA base pairs only when they precisely match the RNA base pairs of the Cas9. If incorrect binding occurs, it only lasts for “milliseconds to seconds before the Cas9 moves on” to the correct match. Finally, since some incorrect matches can occur, particularly to off-target sequences that only differ by a few mutations, the actual cutting will only occur if there is a precise match with the DNA sequence, otherwise the Cas9 protein inhibits it. However, despite these checks, researchers have faced difficulty in using the technology precisely enough to prevent unintended edits through incorrect binding. Alleviating some of the fear of incorrect binding, scientists recently discovered an “off-switch” for CRISPR-Cas9: “anti-CRISPR proteins” that can be used to turn off gene edits. The ability to turn off edits could provide researchers with “a fail-safe to quickly block any potential harmful uses of the technology.” While researchers are continuing to unwind the intricacies of this technology, it nonetheless has the potential to revolutionize the scientific and medical fields. Yet with such revolutionary capabilities, the debate now centres on what diseases CRISPR-Cas9 could alleviate and when researchers will be ready to use the technology.

Beneficial Usages of CRISPR

CRISPR-Cas9 technology holds the potential to alter the world as perceived. From a medical perspective, the technology may have far-reaching effects on the human race as a whole because more than 6,000 diseases have been linked to genes.

One example of an area for treatment is cystic fibrosis, a disease caused by a gene mutation “that causes persistent lung infections and limits the ability to breathe over time.” Though there are about 1,800 different variations in the cystic fibrosis gene, a potential cure would be to employ CRISPR-Cas9 technology to replace the mutant gene with the proper one. A deal was made between the company Editas Medicine and the Cystic Fibrosis Foundation Therapeutics, which is connected to the Cystic Fibrosis Foundation, to provide Editas up to $5 million to develop a medical solution. Intestinal stem cell research has showed promise in preliminary investigations.

The exciting potential of CRISPR-Cas9 to cure haemophilia, a well-known blood condition that results in excessive bleeding, is yet another example. Haemophilia is brought on by genetic changes in an individual's DNA, just as cystic fibrosis. Using CRISPR-Cas9, University of Pennsylvania researchers created a haemophilia therapy and gave it to homophilic mice.

Despite the evidence of beneficial usages, there has been an ongoing debate about the efficacy of gene editing in usages pertaining to treating diseases and preventing them from occurring since the edited genes just like normal ones are capable of inheritance, thus passing down the lineage.[11] Further, questions as to viability commercialization of CRISPR-Cas9 technology still looms around in the Scientific Community.[12]

We shall now move forward to discuss the viability or patentability of germ-line based gene therapy as a process, and moreover, if the organism developed out of such gene editing is patentable as a product.

Legal Framework in India

The fields of law, science, and society are closely related. Science offers next to nothing about morality or ethics, and it offers no guidance on how we should live. It is unquestionably a scientist's duty to advance humankind via technology, but it is not his place to decide whether to use nuclear weapons. Moral, social, and ethical norms of human behaviour must be developed by society as a whole.

In the above context, this section will cover the nuances of Indian Law pertaining to granting of patent, and whether patent either product or process can be granted for Gene Editing technology.

Indian Patent Act 1970 post the recognition of Product patent in 2005 recognizes 3 essentials to be fulfilled for any product or process to become eligible for grant of patent.

1. Novelty
2. Non-Obviousness
3. Industrial Application

When the likes of technology such as CRISPR is looked from the perspective of above 3 essentials, it is an undisputed fact that prima facie it qualifies the test of being novel involving an inventive step not anticipated in by any sources before, and that a person ordinarily skilled

[11] Tara R. Melillo, "Gene Editing and the Rise of Designer Babies" 50 *VAND. J. TRANSNAT'l L.* 764 (2017).
[12] *See id*. at 765.

in the art could not have foreseen such technology as obvious, and finally the commercial viability subject to regulatory approval and stabilization of results achieves through such gene editing is possible.

The problem starts when Section 3 of the Patent Act comes into the whole picture, which subjects the above essentials to the restrictions provided therein.

Section 3(b), Section 3(i), and Section 3(j) are particularly relevant to be discussed as these are the restrictions that pose the ultimate challenge for grant of patent either product or process to Gene editing technologies such as CRISPR-Cas9.

Morality Perspective

Section 3(b) of the Act is reproduced as follows:

"*3. What are not inventions. —The following are not inventions within the meaning of this Act, — (b) an invention the primary or intended use or commercial exploitation of which could be contrary to public order or morality, or which causes serious prejudice to human, animal or plant life or health or to the environment.*"[13]

With reference to the above cited exception to granting of patent, it is said that morality is very subjective differing from society-to-society based on practices and beliefs of common public.

It is imperative to state that what may be legal may not always be moral or conform to the beliefs of a society. Take for example the recently struck down law by the Supreme Court in the case of *Joseph Shine v. Union of India*[14] pertaining to Adultery committed by a married woman, citing the protection of sexual autonomy of an individual under Article 21 of the Constitution. It is the best example of how an Act may be perceived immoral by a society yet may still be legal. Another case scenario is Supreme Court striking down of the offense of Homosexual Sexual Intercourse under Section 377 of IPC in *Navtej Singh Johar v. Union of India*[15] so far as concerned that the consent was existing for such an Act, again citing human dignity and decisional autonomy over an individual's body as being protective under Article 21 of the Constitution.

The Section 3(b) can be said to be incorporated with a positive outlook to cater to the morality of the Indian society and preserve the social fabric. However, a wider interpretation at the

[13] The Patents Act, 1970, (Act 39 of 1970), s. 3(b).
[14] AIR 2018 SC 4898.
[15] AIR 2018 SC 4321.

whims and fancies of the Government despite the fact that what may be legal aligning with fundamental rights may not always be perceived as moral in society, poses a substantial problem for recognition and adequate incentivization to the inventors of new technologies.

The above as hint of doubt becomes true when we look at the current development of Indian Law with regard to Germline Engineering, to say in simple words, the Manual of Patent Office practice recognizes "*inventions relating to cloning of human beings, processes for modifying the germ line and genetic identity of human beings, uses of human embryos for industrial or commercial purposes, and processes for modifying the genetic identity of animals that are likely to cause them unnecessary sufferings as falling under the category of contravening public order and morality.*"[16] Therefore, in the guise of Public Order and Morality, as expected, the government has banned germline gene editing and reproductive cloning.[17] Further there is also a prohibition on clinical trials of xenogeneic cells, which means the cells that belong to members of different or varying species.[18]

The justification provided behind such ban is elaborated in the 2013 Guidelines for Examination of Biotechnology Application for Patent [19] that "the ban is imposed with the view that it may lead to the creation of designer babies, inducing unnatural advantages."[20] Further, the reasoning blatantly states that "Biotechnology deals with living subject matters and involves alteration of genomic materials of an organism. Such change may influence or may have a deep impact upon the environment or the human, animal or plant life or may involve serious questions about morality. Hence, adequate care should be taken while examining the inventions vis-a-vis their primary or intended use or commercial exploitation and it should be carefully dealt so that the subject-matter must not be contrary to public order, morality or causes serious prejudice to human, animal or plant life or health or to the environment. A few non limiting examples may further clarify the issues:

'(a) a process for cloning human beings or animals;

(b) a process for modifying the germ line of human beings;

(c) a process for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical or other benefit to man or animal, and animals

[16] The Manual of Patent Office Practice and Procedure as modified on March 22, 2011.

[17] Akshara Nair, "The Designer Baby Quandary- An Insight Into Gene Editing And Its Legality", *LiveLaw* (2023), available *at* <https://www.livelaw.in/columns/the-designer-baby-quandary-an-insight-into-gene-editing-and-its-legality-222176?infinitescroll=1> (last visited on July 12, 2024).

[18] *See Id*.

[19] Office of Controller General of Patents, Designs and Trademarks, "Guidelines for Examination of Biotechnology Application for Patent" 11 (2013).

[20] Akshara Nair, *supra* note 17.

resulting from such process.
(d) a process for preparing seeds or other genetic materials comprising elements which might cause adverse environmental impact.
(e) uses of human embryos for commercial exploitation.'[21]

In the light of the above guidelines it can be said at present, it is clear that by the virtue of expansive interpretation given to Section 3(b) of Patent Act 1970 there exists a blanket ban on grant of patent over germline technology based CRISPR-Cas9 gene editing method in India due to seemingly it being violative of Public Order and Morality as per the Government of India.

In-spite of the fact that germline-based gene editing technologies are prohibited to be patented irrespective if it's a product or process patent, it is relevant to discuss the possibility of prohibition on grant of patent for such technology under Section 3(i) of the Act.

Patenting Living Organism and Method of Treatment

Section 3(j) of the Act is reproduced as follows:
"*3. What are not inventions. —The following are not inventions within the meaning of this Act, — (j) plants and animals in whole or any part thereof other than micro-organisms but including seeds, varieties and species and essentially biological processes for production or propagation of plants and animals;…*".[22]

The case of *Diamond v. Chakraborty* that happened to extended the scope of granting patent to living organism has also been recognized in Indian Legal system in number of cases starting from the landmark case of *Dimminaco AG v. Controller of Patents and Designs*[23] the interpretation was given to the term "manufacture" under the Act as bearing a general dictionary meaning attributed to the word in the particular trade or business, can be accepted if the end product is a commercial entity. The court further held that "there was no statutory bar in the patent statute to accept a manner of manufacture as patentable even if the end product contained a living organism."

Referring to the above bare language of the section, an express exception excluding micro-organism has been given. It is not the case that gene editing technology such as CRISPR may get covered under this provision, but nevertheless it can be argued under this particular Section that no expansive interpretation to the extent can be given so as to exclude any living thing to

[21] Guidelines, *supra* note 20 at 11.
[22] *Supra* note 14, s. 3(j).
[23] (2002) I.P.L.R. 255 (Cal).

be excluded from patenting specifically talking under this section, not read with any other provision u/s 3. The possibility of patenting a living thing apart from a microorganism shall be discussed in latter part of the paper.

Section 3(i) of the Act is reproduced as follows:
"*3. What are not inventions. —The following are not inventions within the meaning of this Act,* — any process for the medicinal, surgical, curative, prophylactic diagnostic, therapeutic or other treatment of human beings or any process for a similar treatment of animals to render them free of disease or to increase their economic value or that of their products."[24]

The important terminology to be considered in the above language of the section with reference to the Gene Editing is 'Therapeutic' which includes prevention as well as treatment or cure of disease. Therefore, the process relating to therapy may be considered as a method of treatment and as such not patentable. Hence, this particular provision can be said to be restrictive and may act as an impediment when it comes to grant of process patent for CRISPR gene editing technology.

To conclude the discussion on legal framework pertaining to germline-based gene editing technologies like CRISPR-Cas9 irrespective of the immense advantages it holds in eliminating multiple diseases, cannot be patented under current laws for the reasons and analysis aforementioned.

It is necessary to discuss the legality of germline-based gene editing technologies in other prominent jurisdictions like USA and China.

Comparative Analysis with Other Jurisdictions

The three major jurisdictions i.e., USA and China and EU that are pioneers in health and medicinal technologies are chosen for analysis with respect to their legislations on recognition of patentability of Gene Therapy.

USA

An interesting case post the success of *Diamond v. Chakraborty* was that of Harvard Onco Mouse. It was first of its kind patent issue for a transgenic animal (i.e., an animal created by injecting genes from another species into a fertilized animal egg and then surgically implanting the egg into the mother).[25] The injected genes were oncogenes that triggered cancer growth,

[24] *Supra* note 14, s. 3(i).
[25] Pariksha Parmar, *supra* note 5 at 209.

making the oncomouse" a particularly valuable tool for testing the effects of cancer-fighting drugs and suspected carcinogens.

There have been numerous instances where patents on such living transgenic animals have been granted by the US Patent office including examples of Chickens, Dogs, Pigs, Sheep etc.[26]

The above example is with reference to a product patent on a living entity, but that does not extend to human beings even if conceived through artificial assistance and modifications as contemplated in CRISPR Technology usage.

With reference to process or product patent over living organisms, the landmark case is *Myriad Genetics v. Association for Molecular Pathology*.[27] The case at hand concerned granting of a patent to a modified genes for treatment of breast and ovarian cancer, the US Supreme Court in a landmark ruling went on to grant a writ of certiorari on the point that *human genes can be granted patent.* The point of consideration is that the human genes per se cannot be granted patent, but purified or isolated DNA can be.[28]

The USA regulator for approval FDA (Centre for Biologics Evaluation and Research (CBER) that regulates human gene therapies, which fall under the legal definition of a "biologic.") and the ancillary laws concerned[29] allow the extensive trial study for gene therapy products, however, till date no gene therapy product has been allowed to be sold in the USA.[30] Nevertheless, in a breakthrough step, a news has come that the US Patent and Trademark Office recently granted a patent for a technology that would let prospective parents specify the traits of their offspring, from health risks to eye colour. It is the company *23andMe* (a genetic testing company) that has secured a patent on technology that works on the model similar to CRISPR.[31]

China

The publication "An Outline of Quality Controls for Clinical Studies of Human Somatic and Gene Therapy" was issued in May 1993 by the Chinese Ministry of Public Health. In June 1999, after more revisions, it was published again under the title "Guiding Principles for

[26] *Id*.
[27] 569 U.S. 576 (2013).
[28] Pariksha Parmar, *supra* note 5 at 211.
[29] Archisha Satyarthi, *supra* note 9 at 63.
[30] *Id*.
[31] Namrata Maheshwari, "I'll Have One Customised Baby, Please, Thank You': The us Patent and Trademark Office recently granted a patent for a technology that would let prospective parents specify the traits of their offspring, from health risks to eye colour" 51 *EPW* 133 (2016).

Human Gene Therapy Clinical Trials." The Chinese State Food and Drug Administration (CFDA) released a paper titled "Guidance for Human Gene Therapy Research and Its Products" in March 2003 in response to the gene therapy field's explosive growth. This guideline paper described the structure for the research protocol, the requirements for building a recombinant DNA and gene delivery system.

The document also included specifications for the production process, quality assurance procedures, testing procedures for engineered strains and cell banks, as well as tests for product safety and efficacy. Hongzhang Yin released a study in 2006 that addressed China's policies and processes for evaluating and approving new drugs. A summary of the regulatory guidelines for gene therapy research, product development, and commercialization in China was presented in a paper titled "The application of gene therapy in China" by Dr. Peng of Shenzhen SiBiono GeneTech Co. Ltd. in May 2008.

The overall scenario may seem conducive when it comes to the pragmatic approach adopted by China in respect of gene editing technologies. However, that is not exactly the case, wherein we have seen how when a Chinese scientist He Jiankui had claimed to have developed a first gene-edited baby free from the disease of Alzheimer was jailed until being recently released.[32]

EU Model

The EU Clinical studies Regulation of 2014 prohibited any gene therapy clinical studies that alter the germline; however, it made no mention of whether non-clinical research is allowed or prohibited. There are rules prohibiting human germline modification in 15 of 22 EU countries.
The 2000 EU Charter of Fundamental Rights and the 1997 Council of Europe Convention on Human Rights and Biomedicine (Oviedo Convention) serve as the legal and ethical framework for gene therapy throughout the EU. "Eugenic practices, in particular those aiming at the selection of persons," are forbidden under Article 3 of the EU Charter of Fundamental Rights. Oviedo, which was ratified by 29 of the 47 countries in Europe, stipulates that any therapy involving genetic alteration of humans "may only be undertaken for preventive, diagnostic or therapeutic purposes and only if its aim is not to introduce any modification in the genome of any descendants."[33]

[32] Anjali Thakur, "Chinese Scientist Who Gene-Edited Babies Is Back In Lab After Jail Time", *NDTV* (2024) available at <https://www.ndtv.com/world-news/chinese-scientist-who-gene-edited-babies-is-back-in-lab-after-jail-time-5369252#:~:text=Chinese%20scientist%20He%20Jiankui%2C%20who,Alzheimer's%20and%20other%20genetic%20diseases> (last visited on April 12, 2024).

[33] Genetic Literacy Project, "European Union: Germline / Embryonic", *GLP* (2020) available at <https://crispr-gene-editing-regs-tracker.geneticliteracyproject.org/eu-germline-

The limitations on research set by Oviedo are not well understood. It may still be in compliance with Oviedo to use genome editing for medicinal or preventative purposes, provided that the mutation of the descendant's genome is incidental to the process rather than the main objective. It guarantees scientific research freedom subject to human rights protection, which is thought to safeguard researchers' ability to do germline editing as part of pure study. However, whereas Oviedo permits in vitro research on human embryos, Article 18.2 forbids the development of human embryos for scientific purposes. Thus, it is forbidden to conduct the current studies that have shown the genome editing of human embryos in the US, China, Japan, or other nations to eradicate a heritable illness.

Implications of Patenting Designer Babies (The Moral Question)

It is a saying that the law is the one that is supposed to keep up with the developing technologies to accommodate the necessary changes in society and not vice versa. Let's take for example the journey of conferring legal validity to Surrogacy, wherein in earlier times, surrogacy due to ethical and moral issues was completely banned. However, the technological advancement via Assisted reproductive technology offered various advantages to society and infertile couples who may have not been able to conceive child for number of reasons including work life balance in the modern times. Thus, the government recently conferred the legal validity on surrogacy as a practice subject to non-commercialization of such practice. Thus, the twin objective of conforming the law with the contemporary requirements and balancing it with the Moral perspective was achieved.

Another prominent example in the realm of Intellectual Property Rights can be with regard to Cryptocurrency and Blockchain Technology, where despite the numerous disadvantages associated with establishing control and have checks and balances to a decentralized currency system like cryptocurrency, it became the need of the hour that legal recognition was provided to it irrespective of other considerations. Hence, after banning cryptocurrency for a brief period, the Government of India finally concede in accepting the new normal and innovation in technology,[34] additionally, the role of blockchain technology with reference to the IP Management, Smart Contracts for licensing and assignment of IP Rights etc. were also

embryonic/#:~:text=The%20EU%20Charter%20of%20Fundamental,diagnostic%20or%20therapeutic%20purposes%20and> (last visited on May 2, 2024).

[34] Nidhi Bhardwaj, "RBI Gov calls for an outright ban on cryptocurrency as Union Budget 2023 approaches**",** *India Today* (2023), available at <https://www.indiatoday.in/cryptocurrency/story/rbi-gov-calls-for-an-outright-ban-on-cryptocurrency-as-union-budget-2023-approaches-2322146-2023-01-16> (last visited on April 23, 2024); Meghana Maiti, "How Are Cryptocurrencies Taxed? How To Report Crypto Income In ITR?", *Outlook* (2023), available at <https://business.outlookindia.com/personal-finance/tax/how-are-cryptocurrencies-taxed-how-to-report-crypto-income-in-itr> (last visited on May 17, 2024).

recognized by Governmental instrumentalities like RBI, NITI Aayog.[35]

The Fundamental Right Argument

Another prominent aspect in favour of granting patent and legitimization to such technologies roots from the protection of life and liberty of an Unborn child. The Supreme Court in the case of *Unnikrishnan v. State of Andhra Pradesh*,[36] the Supreme Court held that "the right to life includes the right to medical care, which extends to both the mother and the unborn child."
In the case of *Suchita Srivastava v. Chandigarh Administration*,[37] the Supreme Court held that "the right of an unborn child to life and personal liberty is protected under Article 21 of the Indian Constitution. It further observed that the State has a duty to protect the life and health of a pregnant woman and her unborn child. However, the right of an unborn child is not absolute and must be balanced with the right of the mother."

It is the responsibility of the state to promote such technologies as may be useful for protecting the life of an unborn child,[38] on the line of same principle even the amendments were carried out in Medical Termination of Pregnancy Act 1971 with respect to consent and protection to the life of child and mother. Therefore, it can be said that removing the blanket ban on lifesaving technology such as Germline Engineering capable of curing multiple diseases before the child is even born is very much viable in the contemporary times.

Patent Should be Allowed

It is argued in the foregoing context that the technological advancement that have a revolutionary effect of eliminating number of diseases and helping the humans in living a wholesome life such as the germline engineering gene editing techniques where the advantages outweigh the petty disadvantages are of nature that they cannot be restricted by the mere clutches of law without any progressive justification. Hence, it is the need of the hour that no imposition of blanket ban on patenting such products for commercial exploitation in the name of morality be allowed, further, a balance should be struck between incentivizing these beneficial innovations while also countering the immoral or extreme exploitation on a commercial level of such innovations by coming up with a proper policy framework and

[35] Press Release, "NITI Aayog, Oracle, Apollo Hospitals and Strides Pharma Sciences Come Together to End India's Growing Battle Against Fake Drug Distribution", *Oracle* (2018), available at <https://www.oracle.com/in/corporate/pressrelease/niti-aayog-oracle-pilot-real-drug-supply-chain-with-blockchain-iot-2018-09-28.html#:~:text=In%20order%20to%20fight%20the,to%20pilot%20a%20real%20drug> (last visited on May 20, 2024)
[36] 1993 AIR 2178.
[37] (2009) 14 SCR 989.
[38] Komal, "A Study on Right of An Unborn Child With Reference To Article 21 Of The Indian Constitution" 11 *IJCRT* 537 (2023).

regulatory mechanisms. The importance of morality for healthy functioning of society is not meant to be undermined by the way of demanding the allowance of patenting of germline based gene editing technology (especially process patent), but it is rather the intent that a harmonious view be adopted to preserve the moral/social fabric while also catering to the technological advancement by making such changes in the law as has been discussed.

Recommendations for Legal Framework

- Allowing patentability of germline engineering-based technologies.
- Enactment of a separate legislation: It is required for comprehensively regulating the Research and Development in the field of Genetic Engineering. Additionally, forming a regulatory body for overseeing and monitoring the misuse or extreme commercial exploitation of such technologies, beyond the therapeutic usages toward enhancements is also required.
- Incorporation of Specific Ethical Guidelines regarding Germline Engineering: In addition to the existing ones, it is required that comprehensive ethical guidelines addressing the moral implications of germline engineering, emphasizing the importance of informed consent, equity, and non-discrimination be developed.

Conclusion

The concept of designing babies through genetic modification, particularly germline engineering, raises profound ethical, legal, and societal questions. Advances in technologies such as CRISPR have made it increasingly feasible to edit the genes in order to enhance desirable traits in offspring. However, this ability also brings with it significant moral considerations regarding the nature of life and the limits of human intervention in the genetic makeup of future generations.

The legal framework in India faces challenges in addressing the patentability of genetic modifications, including designer babies specifically where any possible interpretation leas to a single interpretation of impossibility of grating patent over gene editing technologies. A comparative analysis with other jurisdictions reveals varying approaches to the patentability of genetic modifications. While some countries have embraced the potential benefits of genetic engineering and allow for patents in this area, others have imposed strict regulations or outright bans due to ethical concerns.

The implications of patenting designer babies are complex and multifaceted. On one hand, allowing patents could incentivize research and innovation in genetic engineering, potentially

leading to significant advancements in healthcare. On the other hand, there are concerns about the commodification of life, discrimination based on genetic traits, and the erosion of human dignity. Considering these, it is recommended that a careful balance be struck between incentivizing beneficial innovations in genetic engineering and ensuring that ethical principles and societal values are upheld. This could be achieved through the establishment of clear regulations and ethical guidelines, as well as ongoing monitoring and oversight to ensure compliance. Overall, the legal framework for germline engineering in India must be developed with a nuanced understanding of the ethical, legal, and societal implications involved. By doing so, India can harness the potential benefits of genetic engineering in ensuring healthy life for all while safeguarding against potential risks and ensuring that the fundamental principles of morality and human dignity are preserved.

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