HUMAN CLONING: THE CHALLENGE OF PATENTABILITY

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ABSTRACT

The history of life form patents shows the momentum of biological advances. There will be numerous brand-new and difficult ethical conundrums surrounding the patenting of human parts and partial paths of human development as we move forward with a greater understanding and technological control of embryonic biology[1]. These issues are already present in the debatethat is currently taking place on the moral standing of the early human fetus.

This research study examines human cloning, including its varieties and the steps involved in creating human beings or human parts. The primary concern of the essay is whether or not human cloning is patentable. The report will outline several nations' perspectives on the patentability of human cloning and further provide light on India's position on the matter.

[1] The study of the formation and development of an embryo and foetus.

INTRODUCTION

Making a genetically identical replica of a human is known as human cloning. The practice ofreplicating human cells and tissue is known as artificial human cloning and is where the phraseis most frequently employed. It doesn't relate to identical twins being conceived and born naturally.

The term "cloning" is defined as "making an identical copy" and has the Greek term "asexual replication of an organism" as its basis. Numerous biological disciplines have used cloning, and clones are cells with genetically identical DNA molecules. Honey bees reproduce by cloning because the queen mates just once throughout her lifetime, and the resulting eggs multiply in the queen up to thousands of times before hatching into bees[2]. Cloning is the term used to describe the procedures used to produce a cell, tissue, or organism with an exact genetic duplicate. A clone is a copy of a substance that shares the same genetic make-up as the original. The most well-known clone was Dolly, a Scottish sheep. After a sheep named Dolly was successfully cloned in 1996 using somatic cell nuclear transfer (SCNT), the concept of cloning humans became a contentious issue. While a few scientists vowed to create a clone within the following several years, many countries forbade it. By using advanced cell technology, the first hybrid human clone was produced in November 1998. It was made through SCNT; a cow's egg had its nucleus removed, and a cell from a man's leg was placed into it. The resulting hybrid cell was then cultivated and turned into an embryo. After 12 days, the embryo was destroyed. The possibility of cloning humans has generated debate. Several countries have passed legislation regulating human cloning as a result of these ethical concerns. Though it had been a topic of conjecture for much of the 20th century, scientists and decision-makers started to examine the notion seriously in 1969. The concept of human cloning was initially proposed by J. B. S. Haldane[3], who did so by using the phrases "clone" and "cloning," which had been used in agriculture since the early 20th century.

TYPES OF HUMAN CLONING AND PROCESS

Reproductive cloning and therapeutic cloning are the two categories of human cloning. Reproductive cloning is used to replicate a human so that the child resembles the parent in

[2] Khorrami J. Consequences and reactions of human cloning. Mobaleghan. 2004; 51:161-73.
[3] British-Indian scientist who worked in physiology, genetics, evolutionary biology and mathematics.

every way. Stem cells from the embryonic clone are grown during therapeutic cloning.

- **Reproductive Human Cloning:**

Somatic cell nuclear transfer (SCNT) is a procedure used in reproductive cloning to create the embryo. With this method, the female donor's egg cells and nuclei are donated. An enucleated egg is produced by removing the egg cell's nucleus. The somatic cell donor is the person who is being cloned. DNA is the genetic material thatshould be present in the somatic cell. Electricity is utilized to fuse the somatic cell andthe enucleated egg in an artificial medium. The infusion of egg cells into the somatic cell is made possible by the high voltage, which creates pores in the somatic cell membrane. The embryo is created as a result of this. After that, the embryo is placed for gestation within the uterus of the surrogate mother. The cloned subject's baby is born by the surrogate mother[4] at the end of the gestation period. However, this treatmentoften has an extremely low success rate, with just one or two of every 1000 embryos making it to adulthood. Instead of only replicating particular cells or organs, reproductive cloning would include creating a human being from scratch.

- **Therapeutic Human Cloning:**

The primary goal of therapeutic cloning is the creation of stem cells from the cloned embryos that will aid in the treatment of numerous illnesses and ailments. Additionally,it helps with organ replacement therapy. Similar to SCNT, the process involves growingstem cells from the embryo's cells rather than implanting the embryo into a surrogate mother. For the corresponding therapy, these stem cells are utilized. In therapeutic cloning, human cells would be reproduced for use in treatments and organ transplants.Even though it is a topic of active research, as of 2023, it is not used in any medical settings worldwide. Somatic-cell nuclear transfer and (more recently) pluripotent stem cell induction are two popular techniques for therapeutic cloning that are currentlybeing studied.

APPLICATIONS OF CLONING

Our understanding of developmental biology, particularly early human development, has

[4] A person or animal that takes on all or part of the role of the mother to another person or animal, or, a woman who bears a child on behalf of another person or a couple, typically via artificial insemination or in vitro fertilization.

improved as a result of work on cloning techniques. Aesthetic and regenerative medicine[5] must enter the area in order to address numerous developmental illnesses and deficiencies that can be addressed with basic knowledge of signal transduction and genetic modification in the early human embryo. SCNT-produced cells are useful for studying the origins of diseases and serving as model systems for the development of new drugs. In the future, regenerative medicine techniques utilizing cells created with SCNT may be utilized in organ regeneration or cell transplantation. Cell transplantation used in the treatment or prevention of a disease or condition is known as stem cell therapy. Stem cell therapy frequently takes the form of bone marrow[6] transplantation. Stem cell therapy is being investigated as a potential treatment for a number of disorders. Autologous stem cell transplantation[7] would be possible thanks to regenerative medicine, which also eliminates the possibility of organ transplant recipient rejection. For instance, to replace a damaged liver in liver disorders, a new liver may be created using the same genetic material and transplanted. Human neurons can be produced from human pluripotent stem cells, which has the potential to advance regenerative medicine for brain and neural injuries.

PATENTABILITY OF HUMAN CLONING

Concerns about this scientific phenomenon and human experimentation were raised in the UNESCO[8] proclamation on the human genome, the 1997 proclamation on Human Rights, and the Strasbourg Convention on Human Rights and Biomedicine[9]. Following the discovery of human cloning, the legislature passed laws addressing the needs, frameworks, resources, and future legal studies, which had far-reaching effects, particularly with regard to concerns about criminal justice and human rights in the third millennium.

In particular, the USPTO's ("USPTO")[10] human being exclusion raises questions about the patentability of inventions resulting from stem cell and human cloning research.

[5] Regenerative medicine seeks to replace tissue or organs that have been damaged by age, distress, trauma, or congenital issues.
[6] It is a spongy substance found in the centre of the bones.
[7] This type of transplantation uses healthy blood stem cells from your own body to replace bone marrow that is not working properly.
[8] United Nations Educational, Scientific and Cultural Organization.
[9] This convention lays down a series of principles and prohibitions concerning bioethics, medical research, consent, rights to private life and information, organ transplantation, public debate etc.
[10] United States Patent and Trademark Office

A patent application was submitted by Professor Hwang[11] based on the findings of his investigation. A pluripotent[12] ES cell line ("SCNT-hES-1") derived from a human blastocyst,a procedure for creating SCNT-hES-1, and/or specialized cells subsequently produced fromSCNT-hES-1, such as neural cells, may all have been covered by Professor Hwang's patents. The Patent Act of US additionally restricts the right to patent inventions to those that are"useful." The term "useful" has often been read widely by the courts, with utility being foundwhenever the revealed invention is genuinely "operable and capable of satisfying somefunction of benefit to humanity. "The utility requirement can be examined more thoroughly bydissecting it into its three parts: general utility, particular utility, and beneficial utility.

- **General Utility**

The general utility question hinges on "whether [or not] the invention as claimed can really do anything," according to the inventor. Replicative cloning is useful for producing genetically identical individuals and as a method of asexual human reproduction. Similar to that, therapeutic cloning is useful in that it offers a way to produce human organs for transplantationthat are genetically exact.

- **Specific Utility**

The ability of an invention to achieve its intended function is referred to as its specific utility. The success in producing cloned organs or humans is the unique utility of inventions involvinghuman cloning.

- **Benefit Utility**

According to one interpretation of the idea of helpful utility, an invention must "have some minimum social benefit, [and not be] completely harmful or deleterious. "However, as Professor Merges astutely points out, this approach has only been applied to activities that were thought to be intrinsically evil (at least at the time) in order to prevent patentability. For instance, in the late nineteenth century, when the general public believed that gambling and

[11] Hwang Woo-suk is a South Korean veterinarian and researcher. He was a professor of theriogenology and biotechnology at Seoul National University until he was dismissed on March 20, 2006.
[12] (Of an immature cell or stem cell) capable of giving rise to several different cell types.

fraud were intrinsically undesirable, useful utility was frequently used to reject patent applications for gambling equipment and fraudulent medicines.

The goals of human cloning do not fall under the definition of "completely harmful or deleterious." Contrarily, both the act of having children and the therapy of organ failure are notonly not fundamentally harmful, but also highly appreciated in society.

Last but not least, inventions involving human cloning are not prohibited from fulfilling the other legal standards for patentability. The novelty requirements of 5 U.S.C. 102, the non-obviousness requirement of 35 U.S.C. 103, and the disclosure and enablement requirements of35 U.S.C. 112 are not unique to human cloning inventions.

PATENTABILITY OF HUMAN CLONING IN OTHER COUNTRIES

Legislative bodies from all over the world have quickly responded to advances in animal cloning and its early applications to humans. Although the majority of these responses were critical, very little of the suggested legislation to control or outlaw human cloning has actually been passed.

I) UNITED STATES

Less than a week after Dolly's cloning was revealed, on March 4, 1997, then-President Clinton[13] said that "no federal agency may support, fund, or undertake [human cloning research]."Until the National Bioethics Advisory Commission ("NBAC") and the entire country "have had a real chance to understand and debate the profound ethical implications ofthe latest advances," President Clinton also urged the scientific and medical communities to voluntarily halt their private human cloning research. Three months later, the NBAC, whose ability to handle the situation has been critically questioned, unanimously denounced the technology and advocated for a nationwide ban on all attempts at replicative cloning[14]. A rushof federal legislation was suggested to criminalize human cloning across the United States, in line with the NBAC's suggestion.

[13] 42nd U.S. President
[14] Creation of a perfect replica.

But as of January 2002, none had been put into effect. The "Human Cloning Prohibition Act of 2001," was approved by the House of Representatives in July 2001 and was anticipated to be discussed in the Senate in February or March 2002. It was to outlaw both therapeutic and replicative cloning.

II) EUROPEAN UNION

The European Union ("EU")[15] has been most successful in outlawing human cloning. When the European Council categorically denounced this technique on May 29, 1997, the anti-cloning stance of the EU was first made public. Then, on January 15, 1998, the EU Parliament urged its constituents to ratify the Council of Europe Human Rights and Biomedicine Convention addition, which forbade human cloning.

Finally, the EU prohibited the patentability of human cloning inventions with Directive 98/44, whose deadline for ratification by member states passed on July 30, 2000. This directive made any method for cloning humans unpatentable on the grounds that "their commercial exploitation would be contrary to public order or morality."

The order was made public in reaction to European Patent No. EP 0695351 given in December 1999 by the European Patent Office to the University of Edinburgh for the "isolation, selection, and propagation of animal transgenic stem cells." The contentious part of the application, claim 48, specifies a SCNT technique that might be used on people. Although the University denied having any plans to participate in human cloning, opponents pointed out that the patent does so because it uses the overly general phrase "animal" without the qualifier "non-human." Due to the directive's explicit phrasing, the University has appealed the decision to invalidate its patent, but success is not anticipated.

III) UNITED KINGDOM

The United Kingdom just made history by becoming the first country to expressly permit human cloning. On November 15, 2001, the High Court declared that as human embryos produced using SCNT do not include the fertilization of an ovum with a sperm cell, they do not meet the statutory definition of "embryo" under Britain's Human Fertility and Embryology

[15] The European Union is a supranational political and economic union of 27 member states that are primarily located in Europe.

Act of 1990[16]. Mr. Justice Crane came to the conclusion that SCNT human cloning is not now illegal. In response, it is rumored that British government officials want to appeal the decision and, in the event that their appeal is unsuccessful, to swiftly create new legislation.

IV) JAPAN

Although Japan has explored a number of legislative proposals to outlaw human cloning research, no legislation has yet been passed. The most recent plan, which the Japanese Cabinet approved on October 6, 2000, calls for fines of up to 10 million yen[17] and prison terms of up to ten years. The proposal does not outright forbid therapeutic cloning; rather, it only forbids the implantation of a human somatic cell into a uterus.

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) is another global agreement on patentability. Article 27 of the TRIP governs restrictions on the patentability of inventions. The article is significant because it gives a thorough description of the security that patentability offers. The article claims that almost all inventions are patentable, regardless of where they are made, whether they may be exported, or what technology they involve, and that they can thus be put on the market alongside other commercial goods. However, there are a few of exception to this general rule. The most important exception— which is required for biotechnological inventions[18]—is "Ordre public and morality." Similarities between this TRIPs rule and Article 53 of the Convention exist. The legal protection of biotechnological inventions is governed by another international agreement, the Directive 98/44/EC of the European Parliament and of the Council on the 6 July 1998 (Directive), which governs the patentability of biotechnological research, including stem cell research. The Directive has received criticism for its ambiguities and shortcomings. The attribution of the Directive as being blocked in a disagreement where it should be explained leads to uncertainty in its interpretation. Therefore, the Directive's interpretation should take into account modern technology and demands.

[16] The act provided for regulation of the creation or use of embryos outside the body; the use of donated eggs or sperm in treatment; and the storage of embryos, sperms or eggs.
[17] Rs. 5,693,912.02
[18] Biotechnological inventions refer to techniques that use living organisms, or parts of them, in order to make or modify products, or to improve or modify certain or all the characteristics of plants, or animals, in order to develop micro-organisms, and organisms intended for specific uses.

PATENTABILITY OF CLONING IN INDIA

Due to exclusions under Sections 3(c) (finding of any living thing or non-living substances occurring in nature) and 3(j) (discovery of any living thing or non-living substances occurring in nature) (plants and animals in whole or any part thereof other than microorganisms), [of Patents Act, 1970][19], patenting stem cells is currently not possible. In India, it is illegal to patent stem cell-based therapies according to Section 3(i), which exempts methods used to treat humans or animals medically.

If a stem cell invention does not fall under Section 3(b) of the Patent Act [1970], it might be patentable. Examples include original and novel synergetic compositions and techniques for processing, differentiating, preparing, and acquiring stem cells. This clause disqualifies inventions from patentability if their application or commercialization would endanger morals, the environment, or the health of living things. Section 3(b) was created as a result of Article 27(2) of the TRIPS Agreement. TRIPS[20] [Trade-Related Aspects of Intellectual Property Rights] contains a disclaimer stating that such exclusion from patentability should not be made only on the grounds that the invention's misuse is unlawful.

The applicant or candidate claimed that the stem cells were obtained from the umbilical cord[21], which is typically discarded after birth, and were extracted with the mother's agreement when a patent application in India, 1492/DELNP/2007, was contested under Section 3(b). The specification included discussion of the cord collecting, and the application was accepted.

CONCLUSION

The term "biotechnology," which is used in the title of the Directive and describes its goal, refers to the application of scientific methodology to apply industrial and commercial processes to biological materials (living cells and microorganisms). This definition matches that of the UN Convention on Biological Diversity's article 2 from 1992. Because investing in biotechnology has a significant level of risk, investors and inventors need legal protection, and entrance barriers should be lowered. As a result, rather than developing a new and special kind of patent for the field of biotechnology, the objective is to manage the restrictions on

[19] Indian Patents Act 1970 is a very limited scope of protection wherein the essential elements of invention were new, useful and manner of manufacture.
[20] Trade-Related Aspects of Intellectual Property Rights.
[21] It is a tube that connects a mother to the baby during pregnancy.

biotechnological material, particularly scientific research involving the human body. By regulating the limitations, it aims to simultaneously encourage biotechnological advancements and achieve a level of development suited to public order and morality, which are governed by local and international laws.

The Directive specifies the subjects that are prohibited and conditioned, as well as whether or not biotechnological inventions are patentable. According to article 3(2) of the Directive, biological elements are patentable if they are taken out of their natural environment.

As can be seen, the Directive governs both the patentability of biotechnological inventions as well as order public and morals. Cloning people, changing their genetic makeup in the womb, utilizing human embryos for production or commerce, and changing the genetic makeup of animals are all seen to fall outside the purview of patent protection.

Though if human cloning is one day made legal to practice, it will undoubtedly have innovative and significant legal repercussions on numerous non-medical facets of society. These include the ambiguous legal status of cloned people, genetic and ova donors, the growth of the wrongful birth doctrine, and the emergence of the crime and potential legal claim known as "genetic identity theft." Due to these factors, legislators and authorities in the domains of tort law, criminal law, family law, and constitutional law will need to review and update respective subjects.