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PATENTABILITY OF EMBRYONIC STEMCELL AND ETHICAL ISSUES IN EMBRYONIC STEM CELL RESEARCH- AN OVERVIEW

A.VEDHA VALLI

FACULTY OF LAW, THE TAMILNADU DR.AMBEDKAR LAW UNIVERSITY, SCHOOL OF EXCELLENCE IN LAW

INTRODUCTION

Stem cell research is a breakthrough in the field of biotechnology. The research was first started in the late seventies and first Embryonic stem cell (ESC) research was successful in the year 1981. It was derived from a mouse. First stage of research was conducted on birds and mouse. Extraction of first Human Embryonic stem cell was reported in the year 1998. Stem cells are pluripotent i.e. they can be developed into different body cells and they can be even cultured into an organ. Any fatal disease in a human body occurs due to death of a tissue or body cells. Diseases like parkinson's, alzeimer's etc are result of death of a body cell or dysfunction of a cell. Stem cells can be developed into any body cells and it can replace the dead cells, hence it can cure the so called "un-curable disease". It can also replace any damaged tissue.

Stem cells are of two types. Embryonic stem cell and Adult stem cell. Adult stem cells are derived through three different ways. 1.Bone marrow 2.Adipose tissue 3.Blood. But adult stem cells are not as flexible as embryonic stem cell and these cells are already committed to be a particular type of cell or a tissue. They lack in versatility. Embryonic stem cells on the other hand are derived from blastocyst stage of a human embryo. Blastocyst stage begins after five days of fertilization but before the implantation in the uterus. These ESC are not committed to develop into any particular type of tissue or cell. Hence they can be molded into any form of cells which can be used to cure degenerative diseases. Extracting Embryonic Stem cell in blastocyst stage makes the embryo non-viable. It is deprived of an opportunity to become a human life. Not all embryos get implanted in the uterus. About fifty percent of the embryos do get implanted. This give raise to many moral and ethical issues.

RESEARCH ON EMBRYONIC STEM CELLS AND LEGAL FRAMEWORK

Many countries, around the world do support and fund researches on Embryonic stem cell as it is a boon to the medical field. Different countries have different rules and restrictions for stem cell research. Some countries decided to ignore the ethical and moral consequences and focus more on the benefit. Some countries have rigid frameworks. Countries like US and Europe are well advanced in Stem cell research. India is rapidly improving in the field of Stem cell research.

In India, ethical guidelines on bio medical research on human subjects were issued by Indian Council of Medical Research (ICMR) in 2000. But these guidelines are non-binding and hence majority of the research were not conducted according to the guidelines. In India research for cloning, implantation of manipulated embryo into the human and non-human uterus are restricted.

In 2017, ICMR issued National Guidelines for Stem cell Research[1]. It seeks to facilitate more ethical and safe mode of research. These guidelines excludes non-human Stem cell research. According to the 2017 guidelines an institution which is conducting stem cell research should mandatorily have Institutional Committee for Stem Cell Research and Institutional Ethics Committee. Institutional Committee for Stem Cell Research should be registered with National Apex Committee for Stem Cell Research and Therapy (NAC-SCRT). Institutional Ethics Committee should be registered with Central Drugs Standard Control Organization (CDSCO). Furthermore studies should be conducted only with Good Manipulation Practice (GMP) and Good Laboratory Practice (GLP) Certified facilities. Medical practitioners who are involved in the research should be registered with Indian Medical Association and have a post graduation degree in the specified field of research. Identity of the donor should be kept confidential. Different level of manipulation of stem cell are also defined in the guidelines. Human participants of the research should not be compelled to pay any charges for the treatment regarding the research.

PATENTING OF EMBRYONIC STEM CELL TECHNOLOGY

Agreement of Trade Related Aspects Of Intellectual Property rights (TRIPs) which was adopted by World Trade Organization (WTO) in the year 1995 under article 27 provides for patentable subject matter. According to which any invention in all fields of technology which is new, involves inventive steps and are capable of industrial applications are patentable. Para two of the article 27 states that member countries may exclude inventions which is against "public order and morality".

In India section 3 of Indian Patent act 1970 provides for non-patentable subject matter. Patenting an embryonic stem cell technology attracts two sub clauses under section 3. Sub clause (b) states that, an invention which is contrary to public order and morality cannot be patented. Patenting an embryonic stem cell may give rise to lot of ethical issues as an embryo has the potential to become a human life. When stem cell is extracted from the embryo it is deprived of its chance of becoming a human life. On the other hand sub clause (j) states that "plants and animals in whole or any part thereof" cannot be patented. The term "thereof" is inclusive, which can be interpreted to include a human embryo as well. Though genetically modified micro-organism can be patented, a human embryo even if it is manipulated it is a part of human body. So as per section 3(j), human embryonic stem cell cannot be patented as such but technology which is used in isolating the stem cell or culturing the cell or purifying the cells etc can be patented. It is to be noted that there is no judicial precedent to explain what constitute part of plants or animals or human body for that matter.

Though patent applications in India for stem cell technology receives objection on the ground of public order and morality, these objections are overcome by excluding any reference to embryonic stem cells from the claims and by disclaiming the use of embryonic stem cells in the operation of the invention. As mentioned earlier ICMR are has issued a detailed guidelines for stem cell research in India, which makes it clear that Stem cell research are not prohibited in India. Although, more safe and ethical methods are recommended. Indian patent office has been following an un-codified principles in examining the patent applications for stem cell technology. India lacks clarity regarding patenting of human embryonic stem cell patents.

United States Patent Trademark Office (USPTO) focuses on the benefits of human embryonic stem cell rather than focusing on the ethical consequences. In US, Wisconsin Alumni Research Foundation (WARF) owns three patents on human embryonic stem cells. First ever patent for HESC was given to James Thomson from University of Wisconsin.

Diamond v. Anand Chakrabarty[2], was the first ever case which granted patent for a living matter. But a naturally occurring micro organism cannot be patented. It has to be genetically modified or manipulated. Human intervention is the basic criteria. Similarly in ***Re Bergy***[3], "biologically pure culture" was considered to be a product of nature and hence patent was granted. Following these two landmark decisions many patents for stem cell technology has been granted. In many instances US supreme Court had made it clear that naturally occurring organisms can not be patented. In may 2013, in ***Association for Molecular Pathology v. Myriad Genetics Inc***[4],

[1] http://dbtindia.gov.in/regulations-guidelines/guidelines/national-guidelines-stem-cell-research-%E2%80%93-2017

[2] 447 US 303 (1980)
[3] 596 F 2d 952 (1979)
[4] 133 ct 2107 (2013)

US supreme court held that, separating a gene from its surrounding material does not amount to inventive step hence patent can not be granted.

In Europe HESC patent was first granted in the year 1999, for University of Edinburgh, soon after which it had grave oppositions. Europe had a rigid framework which was based on "European Directive on the legal Protection of Biotechnological inventions" which was adopted by European parliament in 1998. In 2011, in ***Brustle Oliver v. Green peace*** [5], ESC was declared to be non patentable on the ground that it violates "Human dignity".

Later in ***International Stem Cell Corporation v. Comptroller General of Patent***[6], ICJEU partially lifted its ban on parthenogenetic Stem cell technique. Under this technology, unfertilized eggs are chemically and electrically activated to initiate division of cells. In this case, the court held that "unfertilized human ovum whose division and further development is artificially initiated does not constitute a "human embryo". The court further clarified that human body or an embryo at any stage cannot be patented. It also made it clear that any process which deprives a potential human life should not be made patentable under European Law. Decision in this case tries to strike a balance between encouragement of innovation as well as protecting human dignity.

EMBRYONIC STEM CELL RESEARCH VS HUMAN DIGNITY-AN ETHICAL DILEMMA

It is widely argued that ESC violates human dignity as it takes away a potential human life. The term "dignity" is imperative in debates relating to Cloning, Genetic Engineering, abortion etc[7]. But the term "human dignity" is not defined anywhere. Article 21 of Indian constitution guarantees right to life, which includes right to live with dignity. This has been re-iterated in many instances by our Supreme Court.

During normal course of reproduction only fifty percent of the embryos get to be implanted in the uterus. Some argues that, an embryo which has not yet been implanted in the womb does not have the status of "human". If this argument is accepted then there is no question of human dignity, as an un-implanted embryo is not a human. It does not have any human features or form. It is not a fetus in a women's womb. It is only a cluster of cells. The status of humanity and when a human life begins has been a subject of debate for such a long time. When a personhood comes into being. When life begins is a huge question which remains unanswered.

But every human being started their life as an embryo. It is the early stage of a life. If this argument is accepted then, extracting a stem cell amounts to terminating a human life so is the abortion of fetus. In India, according to The Medical Termination of Pregnancy Act 1971, Termination of Pregnancy is permitted up to twenty weeks of gestation period. Although certain conditions are to be considered for terminating a pregnancy, it is legal to do so. A women has rights to terminate her pregnancy if she does not wants to continue the pregnancy. Every country around the world has their own laws on abortion. It is legal to terminate a pregnancy up to certain time period. If that's the scenario, using an embryo which is not a fetus yet, for the betterment of a living human should not be considered as an ethical violation.

If embryos have the status of "human" then couples who develop embryos for IVF treatment should engage surrogate mothers for each embryo that they develop. As only one or two embryos will be used for the treatment, rest of the embryos are to be discarded. This also amounts to terminating a human life. Though there are other alternatives such as donating the embryos for another couples or using it for stem cell research. Embryos are also preserved in a frozen state for further treatments. If embryos are given a status of "human", then freezing a human being and using it when needed also gives raise to ethical issues. Though it can be said that it is "preserved" not killed, chances are more that preserved embryos loses its viability and ends up being discarded.

Every country throughout the world agrees that Stem cell technology is a boon to human kind and they support stem cell research but some countries emphasis more on ethical consequences of using an embryo for s research. If Human embryo is used for stem cell treatments, then it will be treated as a property. Human being or any body

[5] c-34/10, 2011.
[6] C-364/13,2014
[7] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2726839/

part thereof should not be treated as a property. For this reason some countries have rigid frameworks, though it is not prohibited, more safe and ethical alternative is suggested.

It is universally accepted that right to respectful treatment is more important than right to life. Even a diseased person has right to respectful treatment. If embryos are considered as human life then it also has right to be treated respectfully. But what respectful treatment can a embryo have?. An embryo should not be frivolously killed. It should be destroyed only if it absolutely necessary to do so and also an embryo should not be treated as a property and it should not be traded for monetary benefit.

CONCLUSION

HESC research is no doubt a great blessing for human kind. It is a great breakthrough in medical field. Governments around the world has different levels of framework for embryonic stem cell research. But a major ground for the opposition is ethical aspect of ESC. Alternative approaches are being developed by the researchers such as deriving ESC from umblical chord and amniotic cell lining which is usually discarded after a child birth. India is in its infancy stage in alternative approaches but advancement can be expected soon as the researches are fast developing. Though research on ESC gives raise to ethical issues, the benefit that human kind acquires, outruns the ethical issues. Every human being has right to lead a healthy life. Through ESC technology many so called un-curable disease can be cured. After all betterment of living being is the ultimate goal.