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A MORAL AND LEGAL DILEMMA REGARDING THE STATUS OF HUMAN EMBRYOS IN STEM CELL RESEARCH AND PATENTING

Prashant Kumar Pushkar[1]

ABSTRACT

Stem cell research has given hope to medical fraternities and patients too in finding remedies for such diseases till now considered incurable. This research gained momentum during the latter decades of the twentieth century. The year 1998 was a landmark in medical history when James Thomson of the USA got success in establishing a stem cell line from the human embryo. For such a new invention he got a patent too in the USA. But the fact of destruction of the human embryo in extracting stem cells raised the ethical and moral issues of the commodification of the human body. This issue gave rise to another issue in ascertaining first the moral as well as the legal status of the human embryo itself. Some people have argued that human embryos should not be used for any commercial purpose because it is a living things since fertilization. But many people say that till the time it is implanted in the uterus, it can be used as raw material for research purposes. And if something new is invented then a patent should also be granted due to the high cost involved in this research. Since there is uncertainty as to the extent of permissibility to use human embryos in stem cell research and the eligibility to get a patent for the resultant product, this paper is an attempt to analyze the legal and moral status of the human embryo.

Keywords: IVF, Stem cell, Patent, Fertilization, Human Embryo.

Introduction

Stem cells are undifferentiated cells that can divide to produce some offspring cells that continue as stem cells and some are destined to differentiate and become specialized. Thus, stem cells are an ongoing source of the differentiated cells that make up the tissues and organs of animals and plants.[2]

[1] Ph. D. Research Scholar (2021-2022) Chanakya National Law University, Patna.

[2] Jonathan M.W Slack, Stem cell | Definition, Types, Uses, Research, & Facts, Britannica (Jan. 20, 2022, 3:43 P.M.), https://www.britannica.com/science/stem-cell.

Stem cells contribute to the body's ability to renew and repair its tissues. Unlike mature cells, which are permanently committed to their fate, stem cells can do both i.e., renew themselves as well as create new cells of whatever tissues they belong to.[3]

In the human body, there are two types of stem cells – 1st an embryonic stem cell, and 2nd is an adult stem cell or somatic stem cell. The basic difference between the two is that adult stem cells can formulate only that type of stem cell, to which they belong-, whereas it is the unique characteristics of embryonic stem cells to differentiate into any type of cell in the human body. It is this uniqueness of embryonic stem cells that brings into the picture the legal and moral status of the 'human embryo' because while extracting stem cells the human embryo itself is destroyed. In comparison to 'adult stem cell research', the differentiation capacity of 'embryonic stem cells' is much better and therefore the scientific community's first choice is 'human embryo'.

The 'embryonic stem cells' are derived from 'spare embryos' that develop from eggs, fertilized in-vitro through in vitro fertilization(IVF), and then donated for research purposes with the informed consent of the donors. They are not derived from eggs fertilized in a woman's body as is a common perception.[4]

Since the 'human embryo' is the starting point of human life, so the moral, as well as the legal status of human embryos, obviously comes into question whenever used as raw material for stem cell research. Many people, opposing the use of human embryos for scientific research, say that it is immoral to destroy the human embryo, whereas the supporters of such scientific research have the view that the human embryo has no status at all till it's taking birth alive and therefore there is nothing wrong in the use of the human embryo in such research.

Further, in the light of growing use of the IVF technique by maternity clinics, the clandestine use or transfer of human embryos to the research institute for stem cell research cannot be ruled out. Therefore, in the background of the above facts and situation, this paper analyses the legal as well as the moral status of the 'human embryo' and also the ethical issues in human embryonic stem cell patenting.

[3] Jay W. Marks, Medical Definition of Stem cell, Medicine Net (Jan. 20, 2022, 4: 10 P.M.), https://www.medicinenet.com/stem_cell/definition.htm.
[4] NIH STEM CELL INFORMATION, Stem Cell Basics, National Health Institute (Jan 23, 2022, 4:14 P.M.), https://stemcells.nih.gov/info/basics/stc-basics/#stc-II.

Moral Status of human Embryo:

Human embryonic stem cells are of scientific and medical interest because of their ability to differentiate and to be used in the laboratory for therapeutic purposes. So, the potential of being beneficial to so many people, affected by a serious disease, is a strong argument for doing embryonic stem cell research.

But, this research is also opposed by many people on the ground that this research ultimately destroys the human embryo. So, the morality of embryonic stem cell research depends primarily on the morality of destroying the 'human embryo', raising the question of the moral status of the 'human embryo'. Now, is there any definition of 'human embryo'? According to *'National Guidelines for Stem Cell Research, 2017'*, 'the human embryo' has been defined as a developing stage from the time of fertilization till the time of the eighth week of gestation after that it is known as *'foetus'* till its birth. For stem cell research, the guidelines also define *'early embryo'* as the stage of development from the time of fertilization up to 14 days.[5]

The moral status of the 'human embryo' revolves around two fundamental principles, namely, the duty to prevent the suffering of human beings and the duty to respect the value of human life.

However, it is a very strange situation that in the light of the latest scientific knowledge, both the above-said principles cannot survive simultaneously, as, the fertilized human eggs at the pre-implantation (blastocyst) stage i.e., the early embryo must be destroyed to procure stem cell lines and resultantly, favoring the first principle.

Generally, there are three main propositions regarding the moral status of the 'human embryo':

1. *Full Moral Status*: The supporters of this position have a strong belief that the 'human embryos' deserve the same level of protection as adult human beings. Their argument is based upon the premise that since, a development point, at which personhood is acquired, cannot be pinpointed, a 'human embryo' deserves protection from the point of fertilization. If our lives are worthy of respect simply because we are human, it would be mistaken to think that at some younger age or earlier stage of development (for example, whenwe began our lives as fertilized eggs) we are not worthy of respect.[6]

[5] Department of Biotechnology, Ministry of Science &Technology, Govt. of India, https://dbtindia.gov.in/sites/default/files/National_Guidelines_StemCellResearch-2017.pdf (last visited April 21, 2022).

[6] Kristina Hug, *Therapeutic perspective of human embryonic stem cell research versus the moral status of a human embryo-*

They argue that the 'human embryo' differs from adult human being not in what they are, but only in their stage of development. So, if one permits the destruction of a fertilized egg or pre-implantation stage embryos, then, the same treatment should follow with foetus or infants or every human being missing certain cognitive faculties. Thus, since, the 'embryo' has the potential to develop into a complete human being, it must be awarded the moral respect and dignity that personhood requires.

A *'human embryo'* contains within itself the capacity to develop into a complete human being. Moreover, 'human embryos' are part of the human story because every human being begins life as an embryo. If the entire life of a human being has intrinsic value, then, it is very reasonable to accord value to the very beginning stage of that life.

Thus, the supporters of full moral status for the 'human embryo' say that the law and policy should proceed based on full moral respect for human beings irrespective of age, size, and stage of development or condition of dependency. Embryonic human beings should be treated as subjects of moral respect and not as an object that may be damaged or destroyed for the benefit of others.

So, embryonic human beings, whether brought into existence by the union of gametes, somatic cell nuclear transfer, or other techniques, should be accorded the status of inviolability recognized for human beings in other developmental stages. Public policy should protect embryonic human beings and certainly not mandate or encourage their destruction.[7]

2. *No Moral Status*: The supporters of this proposition have the opinion that a 'human embryo' is nothing but a bunch of cells. The 'human embryo' itself has no intrinsic value or status, until, at least birth, and therefore any research involving 'human embryo' resulting in its destruction does not involve any wrong.

   According to these proponents, the traits that are most central to the concept of personhood are: the capacity to experience pleasure and pain, consciousness, the capacity for reasoning, self-motivated activity and the capacity to use language and the 'human embryos' have none of them. Since *'human embryos'* have none of the above-mentioned person-making characteristics, so, they cannot be members of the moral community and thus, may be used as an instrument for the benefit of others, who are persons. Ultimately, the embryos cannot have moral status at all and

does one has to be compromised for the other?, 42, Medicina (kaunsas), 107, 108-109(2006).

[7] Robert P. George & Alfonso Gomez-Lobo, *The Moral Status of Human Embryo*, 48, Perspect. Biol. Med., 201, 208-209(2005).

they are merely the property of the person from whose body they comeout.[8]

3. *Limited Moral Status*: Between the two above-discussed extreme positions, the proponents of 'limited moral status' hold the opinion that the embryo has a status resting somewhere between full and none. This position is also called *the 'proportional status position'*,which holds that the moral status of the embryo increases with its development of it until it obtains full moral status at birth or beyond.

   The 'proportional status position' also has one peculiarity: by taking a middle position, on the one hand, it neither prevents scientific research nor, on the other hand, gives a free hand to use the 'human embryo' at any stage of its development. So, the proportional status position is more specific. The closer to birth, the greater protection is granted to the embryo and the greater justificatory burden is placed on those who wish to destroy embryos.

   The goal of granting "proportional moral status" to the "human embryo" and the resulting restrictions is to create a legal framework that discourages scientists from using largenumbers of embryos solely to maximize their interests.[9]

Legal Status of Human Embryo:

The legal status of a 'human embryo' for stem cell research and patenting is closely connected with its moral status. Whenever we try to determine whether an 'embryo' is a legal person or not then always a question is raised whether, in the eyes of law, an embryo is capable of holding rights and also enforcing other's duties towards it.

Since an embryo is a unique organism, so, when we talk about its right, we can better understand it in terms of ‘interest’. Here, the term 'interest' has a dual aspect, first, having an interest, and second, taking an interest. The first aspect is directed towards the state, society, and parents; whereas the second one is directed towards the ‘human embryo’.

The reason for proposing the above interpretation is that in the current legal framework, particularly in the Indian context, there is surely confusion, about whether an embryo, being an unborn person, is having interest or not. Though, various statutes have fixed an upper age limit of 18 years while defining a child but have not fixed or defined the lower threshold to clarify whether to include 'an embryo’ in these definitions. But in the context of the second meaning i.e. taking an interest, the state, society, and parents surely take interest in the embryo. Since

[8] Bonnie Steinbock, *Moral Status and Human Embryos*, VI, Steinbock, 416, 427-428(2006).
[9] Shaun D Pattinson, Medical Law and Ethics, 359-360(Sweet and Maxwell 2013).

the embryo develops in the mother's womb, society as a whole cares for the expectant woman because only a physically and psychologically healthy mother can give birth to a healthy child. But when the parent or society fails in their responsibility to "take an interest" in the embryo, the State steps in to fill the gap through law or legal precedent.

Since the entire biological process of embryological development takes place inside a woman, she has full autonomy and discretion over her body regarding whether to start a human life or not. This reproductive right has been recognized within the meaning of Article 21 of the Constitution of India. The Supreme Court of India in a *Case*: *Suchita Srivastava vs. Chandigarh Administration*[10] held that a woman's right to make a reproductive choice is a dimension of personal liberty under Article 21 of the Constitution of India. Here, the reproductive choice can be exercised to procreate as well as to abstain from procreating. It also includes that there is no restriction whatsoever on the exercise of reproductive choices a woman's right to refuse participation in sexual activity or the insistence on the use of contraceptive methods. She is also free to choose birth control methods such as undergoing sterilization procedures.

Further, in another *Case*: *Devika Biswas vs. Union of India and Ors*,[11] Supreme Court of India again observed that the right to health is an integral part of Article 21, which includes the right to reproductive health. Reproductive health means the capability to reproduce and the freedom to make informed, free and responsible decisions.

Thus, it can be said that a woman has full freedom and right as to whether and when to start another life, but such decision has to be very responsible. The reason is that once she decides to become pregnant and bears a child then there come many restrictions, in the form of laws and regulations; on her to behave responsibly as she is not now alone rather she is now carrying another life in the form of an embryo within her.

Two factors work here - (1st) once she decides to go ahead with the pregnancy, restrictions also come in the form that she cannot now fall back as per her wish alone, as no fundamental right is absolute and so the right of reproduction is also not. And, (2nd) after the pregnancy of a woman, apart from her and her family, the state also takes interest in her and her to-be child.

The compelling interest of the state comes in many forms, but, there are two prominent laws

[10] Suchita Srivastava vs. Chandigarh Administration (2009)9 SCC 1 (India).
[11] Devika Biswas vs. Union of India and Ors (2016)10 SCC 726 (India).

in this regard. The first law is the 'Medical Termination of Pregnancy Act, of 1971[12] that allows legal abortion in certain specified conditions such as a risk to the life of the pregnant woman or the possibility of serious abnormalities in the unborn child. The second one is the Preconception and Prenatal Diagnostic Techniques (Prohibition of Sex Selection) Act, of 1994[13] that is used by the state in protecting the interest of the prospective child. It ensures that the scientific technology useful in diagnosing the disease may not be used for sex determination leading to female foeticide.

The MTP Act, of 1970 has tilted the balance in favor of pregnant women up to 24 weeks as amended in 2021[14] although the opinion of two doctors is mandatory. So, it can be said that the compelling interest of the state in protecting the interest of the unborn person has been restricted in certain conditions.

Further, the Indian Penal code, of 1860[15] also protects the interest of the unborn child by criminalizing an act of miscarriage. Particularly, in Section 312 and Section 315, which provide that if any person (including a pregnant woman) has voluntarily caused a pregnant woman to miscarry in bad faith or an act to cause such child to be born dead or causes to die soon after its birth and does such act in bad faith then in the former case, such person is punishable with 3 years imprisonment or fine or both and if the woman was quick with the child then 7 years imprisonment or fine or both, and in the latter case, the punishment would be up to 10 years imprisonment or with fine or both.[16]

However, Section 299, Explanation 3 of the Code, 1860 has strengthened the State's compelling interest in the sense that causing the death of a child has been declared as culpable homicide irrespective of the fact that whether the such child had breathed or not any part of such child has come out of the body of the mother.[17] But, this provision also operates when any part of the unborn child has separated from his/her mother.

Further, Section 416 of the Criminal Procedure Code, 1973 is also relevant in the sense that ifa woman sentenced to capital punishment is found to be pregnant then, the High Court shall

[12] The Medical Termination of Pregnancy Act, 1971, No. 34, Acts of Parliament, 1971 (India).
[13] The Pre-conception and Prenatal Diagnostic Techniques (Prohibition of Sex Selection) Act, 1994, No. 57, Acts of Parliament, 1994(India).
[14] The Medical Termination of Pregnancy (Amendment) Act, 2021, No. 8, Acts of Parliament, 2021(India).
[15] The Indian Penal Code, 1860, No. 45, Acts of Parliament, 1860.
[16] *Id.*, ss.312, 315.
[17] *Supra* note 165, at 81, s.299, Explanation 3.

commute the sentence to imprisonment for life.[18] Thus, this code directly protects the interest of the fetus.

So far as 'property rights' are concerned, though, an interest can not be transferred in favor of an embryo (unborn person) but, according to Section 13 of the Transfer of Property Act, 1882, an interest in any property can be transferred for the benefit of an unborn person provided prior interest is created and the remaining interest is transferred in favor of unborn person but subject to the condition of his taking birth alive before the expiration of last prior interest. And under Section 20 of the Act, 1882, such an unborn person takes a vested interest in such property only after his birth.[19]

Regarding succession, the relevant provision is section 20 of the 'Hindu Succession Act, 1956', which talks about the right of an unborn person to get a share in the property of the intestate, if he was in the womb at the time of death of the intestate. So, in such a situation, if he is born alive then, the inheritance shall be deemed to vest in such a case with effect from the date of the death of the intestate.[20]

Further, under Hindu law, the laws of partition also give a special right to an unborn child contingent upon his taking birth alive. A son/daughter, who was in his mother's womb at the time of partition, is entitled to a share, though born after partition and if no share is reserved then, he/she is entitled to have the partition reopened. A son/daughter, who is begotten and born alive after the partition is not entitled to reopen the partition if his /her father reserves a share to himself, but if not, then, he/she is entitled to have the partition reopened.[21] If we talk about the situation in the U.S.A., it appears that its legal system has treated the 'embryo' only as an integral part of the woman bearing it and so, given no separate rights independent of such woman. However, in certain exceptional situations the courts have recognized the rights of foetus, similar to an adult person, but, it has ultimately created an adversarial relationship between the woman and the fetus by granting the State the power to regulate a woman's behavior during pregnancy.[22]

The U.S. Supreme Court in 1973 in a landmark *Case: Roe vs. Wade* observed that the unborn has never been recognized in the law and the law has been reluctant to afford any legal right to

[18] The Criminal Procedure Code, 1973, s. 416, No. 2, Acts of Parliament, 1974 (India).
[19] Transfer of Property Act, 1882 ss. 13, 20, No. 04 Acts of Parliament, 1882 (India).
[20] Hindu Succession Act, 1956 s. 20, No. 30, Acts of Parliament, 1956(India).
[21] Prof. U. P. D. Kesari, Modern Hindu Law, 428 (Central Law Publications 2011).
[22] Siddtharth Singh Nehra & Abhay Singh Rajput, *The legal personality of an Unborn Child: A Comparative Analysis of USA & India*, 5, AIJJS, 95, 101-102(2019).

foetus except in narrowly defined situations and except when the rights are contingent upon live birth. This judgment had given abortion right to women before the unborn child is viable outside the womb of the woman or before 24 to 28 weeks. There is a common belief that a woman's rights can be distinguished from an unborn child's rights at the point of foetal viability but not before that. So, it can be said that even the law does not recognize an unborn person till the point it attains viability and that's why abortion was legally permitted.

But, recently in June 2022 the US Supreme Court overturned the above case in *Thomas Dobbs vs. Jackson Women's Health Organisation*. The effect of this judgment is that a woman's autonomy over her body has been curtailed and her right to have an abortion has to be decided by the laws of individual states.[23] So, the current position in the USA is that the balance has again tilted in favour of the unborn child to curtail woman's right to privacy but without declaring them as legal person.

The position in England is that a foetus is not a person until it is born alive. It was stated in a *Case: Paton vs. British Pregnancy Advisory Service Trustees* that the foetus cannot in English law have any right of its own until it is born and has a separate existence from the mother.[24]

As a result, when we examine the legal status of "an embryo" in the context of the aforementioned legal framework, we discover that no one has given "an embryo" a clear-cut legal status. Even in those areas of civil law where it has been granted some rights of action, it has been made subject to taking birth alive. By implication, it follows that 'an embryo' has no legal personality before birth and acquires legal status only upon being born alive.

The ethical aspect of Stem Cell Research and Patenting involving Human Embryo:

The area of 'stem cell research' is related to health issues. Due to the development of science and technology, many health's related technologies were developed by the scientific community. Such new products/processes got patents too after fulfilling the conditions of novelty, inventive step, and utility. However, in most of them, the remedy was found outside the human being.

When stem cell technology was developed, then, it found the remedy for many diseases in that

[23] Payal Shah, *The impact of the US Supreme Court's overturning of Roe v Wade will be felt acutely by marginalized people, including low-income women and women of colour, The Impact of US Supreme Court's overturning* (June 28, 2022, 9:00 A.M.) https://indianexpress.com/article/opinion/columns/us-supreme-court-roe-v-wade-abortion-rights-7992611/

[24] Paton vs. British Pregnancy Advisory Services Trustees [1978] 2 All ER 987, 989.

stage of human development, where human life itself begins, i.e., the human embryo. However, this discovery itself is not problematic.

The real issue is that to keep the efficiency and differentiation potency of ‘stem cells' at the maximum level, it is needed to be extracted from an early stage of the embryo, called a blastocyst. But, after such process, the embryo becomes useless, in other words, the embryo then cannot be developed into a human being. It is this problem, which creates an ethical barrier to the research and development of stem cell technology. Dramatically, it can be said that the cure of many diseases by giving a new life to one person by way of stem cell therapy is based on the destruction of another life having the potential to develop into a human being.

Now, the uncertainty regarding the moral as well as the legal status of human embryos appears to have given the State ample scope to allow the use of 'spare embryo' in stem cell research and also to claim a patent. Some examples are discussed below.

In India, the *‘National Guideline for Stem Cell Research, 2017’*, in Section 8.3 clearly says that stem cell research regarding in vitro culture of intact human embryo, beyond 14 days of fertilization or formation of the primitive streak, whichever is earlier, is prohibited.[25] But, Section 4.1 of the guideline, 2017 clearly says that before using such 'spare embryos', it is mandatory to obtain informed consent from the voluntary donor including video consent as per the Central Drug Standard Control Organization guidelines for audio-visual recording dated 9th January 2014.

Since the donation of *‘spare embryos’* raises ethical and moral concerns, therefore, it is necessary to ensure that the donors are neither exploited nor there commoditization of 'human embryos'. It also clearly says that if the use of 'spare embryos' bring any benefit, then, the effort has to be made to pass on the same to the donor but, the ‘intellectual property rights’ will not vest with the donor.[26]

Moreover, the issue of the availability of 'spare embryos' has also been taken care of under Section 8.2 of the guidelines, 2017, where the creation of a ‘human embryo’ by way of any method has been restricted to the extent that the researcher has to prove beforehand that the proposed research cannot be carried out with the existing Embryonic Stem Cell lines or can not be derived from ‘spare embryos’. This limited permission to create human embryos is further

[25] *Supra* note 155 at 76, s.8.3
[26] *Supra* note 155 at 76, s.4.1

absolutely restricted in the form of a complete prohibition on reproductive cloning.[27]

Further, under Section 15.2.4 of the guidelines, 2017, the commercialization of the 'spare embryo' has been diminished by providing that there has to be no inducement by way of payment or instead of medical expenses for such donations except for reimbursement of reasonable expenses for travel and loss of wages of the donor and that too to be determined by the Institutional Committee-Stem Cell Research/Institutional Ethics Committee.[28]

In Britain also, embryo research is permitted only up to 14 days after fertilization or the appearance of the primitive streak, whichever is earlier. The 14 days period is, to begin with, the day on which the process of creating the embryo began.[29]

Similarly, the 'National Institute of Health Guidelines for Human Stem cell Research, 2009, applicable in the United States of America, though, specifically does not point out the 14 days limit but does provide that any human embryonic stem cell research being eligible to get NIH funding, a such embryonic stem cell must have been derived from the inner cell mass of blastocyst stage of human embryos. Thus, by implication, the position in the USA is that the cut-off point has been further limited up to 5 to 6 days from the time of fertilization.[30]

Further, the *'Guidelines for Stem Cell Research and Clinical Translation, 2016'* prepared by the *'International Society of Stem Cell Research'* prohibits in vitro culture of any intact human pre-implantation embryo or organized embryo-like cellular structure with human organismal potential beyond 14 days or formation of the primitive streak, whichever occurs first.[31]

Here, it is important that in all the guidelines and legal frameworks discussed above, 14 days limit has been placed on stem cell research involving 'human embryos'. This position may be based on the fact that a 'human embryo' becomes worthy of protection at around 14 days after fertilization. Many reasons are given in support of that. It is shown under embryological studies that 'fertilization' itself is a process and not a moment and so, 'an embryo', in the earliest stage is not sufficiently individualized to have the moral weight of personhood. It is also argued that it is the implantation of the blastocyst in the uterus wall that is the best landmark for the

[27] *Id.*, s.8.2
[28] *Id.*, s.15.2.4
[29] Legislation.gov.uk, http://www.legislation.gov.uk/ukpga/1990/37/section/3 (last visited April 21, 2022).
[30] National Institute of Health Guidelines for Human Stem cell Research, 2009, https://stemcells.nih.gov/research-policy/guidelines-for-human-stem-cell-research (last visited April 21, 2022).
[31] International Society for Stem Cell Research, https://static1.squarespace.com/static/611faaa8fee682525ee16489/t/62ed69b184e2ed258e6eb7e4/1659726257773/isscr-guidelines-for-stem-cell-research-and-clinical-translation-2021.pdf (last visited April 21, 2022).

definition of human life because after that twinning is not possible anymore. Also, it is from the 14th day that the formation of the central nervous system starts to develop, and only then the possibility of sensation can be said to exist in the human embryo.[32]

Thus, for stem cell research, it can be said that the 'human embryo' has *'proportional moral status'*, and the protection of the 'human embryo' increase with its gradual development. Its moral status of it also increases with its further development not only in the eyes of society but also in the law. As can be seen in India and other legal regimes mentioned above the use of spare embryos only is permitted under certain conditions for stem cell research and if a new product is invented then it may be granted a patent too subject to fulfillment of patentability criteria. Thus, the moral status of the 'human embryo' as well as the extent of the permissibility of stem cell research using it has been fixed up to 14 days.

Now, the extent of permissibility to use *'human embryo'* affects the patentability of a new stem cell product. Unlike in European Patent Organization, new stem cell product is patentable in India. Though, there is Section 3(b) of the *Patent Act, 1970* that excludes any invention from patent, the commercial exploitation of which is against morality.[33] But it appears that the morality aspect has been tiled in favor of scientific research in India.

However, in Europe, under Article 53(a) read with Rule 28 (c) of the *European Paten Convention, 1973*, a patent cannot be granted for an invention that necessarily involves the use and destruction of the human embryo. In other words, there cannot be patenting of claims directed to a product, which at the filling date could be prepared exclusively by a method, which necessarily involved the destruction of the human embryo from which the claimed product was derived, even if the said method is not part of the claim and also that grant of the patent would be contrary to public order or morality if the embryo has been destroyed. Moreover, the human embryo cannot be used for industrial or commercial purposes.[34]

The reason for such prohibition in Europe is an interpretation given in a *Case*: *Oliver Brustle vs. Greenpeace*.[35] In this case, it was held that the term 'human embryo' includes any human ovum after fertilization, if that fertilization is such as to commence the process of development of a human being.

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[32] *Supra* note 156, at 76.
[33] The Patents Act, 1970, s.3 (b), No.39, Acts of Parliament, 1970 (India).
[34] European Patent Convention, 1973 https:// texts/html/epc/2020/e/EPC_conv_20221101_en_20221101.pdf (last visited March 02, 2022).
[35] Oliver Brustle vs Greenpeace, https://eur-lex.europa.eu/legal- Content/EN/TXT/PDF/? Uri=CELEX: 62010CJ0034& from=EN (last visited March 06, 2022).

The same is the situation in Britain with certain modifications. In Britain, the use of human embryos for industrial or commercial purposes is not patentable. Since "human totipotent cells" can evolve into the full human body, they are also not patentable because the human body, in all of its developmental and morphological stages, is not subject to patent protection. Also that the use of cells derived from a procedure that necessitates the destruction of a "human embryo" in the course of putting an invention into practice prevents the patentability of such a process. The stage of destruction doesn't matter in this case. But, 'human stem cells' not derived from 'human embryo', like adult stem cells, induced pluripotent stem cells, will be granted patent protection subject to the condition that they fulfill other conditions of patentability, which also includes parthenogenic pluripotent stem cells.[36]

In the U.S.A., there is no barrier to patenting 'human embryonic stem cells, irrespective of the fact, whether in the process of extracting the stem cell, the embryo was destroyed or not. The morality restriction regarding stem cell research and patenting of the product derived from that research is very flexible. The only limitation is in the form of getting funds from the government and that too when the fund is needed for research using human embryonic stem cells (*hESC*) and certain use of induced pluripotent stem cells.

In the U.S.A. government fund is available only for stem cell research involving human embryonic stem cell, where such stem cell was derived from embryos created by IVF for reproductive purpose and are now no longer needed. Also that such spare embryo was donated for research purpose with informed consent. Thus, if the human embryo has been created for stem cell research by any method other than as mentioned above then it will not get funds from the government.

However, to get a patent on stem cell products there is no such restriction if the conditions of patentability are fulfilled. One other situation also emerges and that is there is no prohibition on private research on human embryonic stem cells, even if a human embryo was created specifically for research purposes except that this research will not get funds from the government. However, in all other respect, any new stem cell product is well qualified to get patent protection subject to the fulfilment of patent criteria.

In fact, in the USA the first 'human embryonic stem cell' patent was issued to 'James Thomson'

[36] Statutory guidance Inventions involving human embryonic stem cells: 25 March 2015, https://www.gov.uk/government/publications/inventions-involving-human-embryonic-stem-cells-25-march-2015/inventions-involving-human-embryonic-stem-cells-25-march-2015 (last visited March 8, 2022).

from the ‘Wisconsin Alumni Research Foundation’ in 1998. After that two more patents were granted to him in 2001 and 2006 respectively, and the assignee of these patents was the 'Wisconsin Alumni Research foundation'.[37] Here, the field of the invention was primate embryonic stem cell cultures.

Conclusion

From the above discussions, it is clear that, so far as moral status is concerned, the human embryo has been conferred limited moral status. It appears that human beings have compromised their level of morality to some extent concerning stem cell research except in certain legal regimes such as Europe. But in the context of legal status, some discrepancies are found. In certain laws dealing with legal rights and liabilities, the upper limit is fixed for a child which is 18/21 years. But whether the embryo is included in that is not expressly mentioned. Though, some abortion laws have fixed upper limits ranging from 20 to 24 weeks for not disturbing the development of human embryos except in certain conditions. But that does not automatically confer legal personality on a human embryo till it takes birth alive. Perhaps, this is the gap in the law that has given scope for human embryonic stem cell research. But this again is opposed on the ground of commercialization and interference in the law of nature.

However, this ethical problem can be lessened by taking some positive steps. The lower threshold of definition of the child should be mentioned in the patent laws itself instead of guidelines/regulations. Further, due to the development of science and technology, many alternative sources are now available, e.g. induced pluripotent stem cells, adult stem cells, and umbilical cord blood. These resources can be used to break the ethical barrier. Moreover, since abortion is legally permitted in many countries including India so, the aborted foetus can also be used to extract stem cells. Though, the stem cells so extracted may not have a high level of potency as compared to embryonic stem cells. Still, this can be a great substitute for embryonic stem cells thereby lessening the ethical burden on the humanities.

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[37] U.S. Patent Nos. 5340740, 5656479, 5843780, https://patft.uspto.gov (last visited March 18, 2022).