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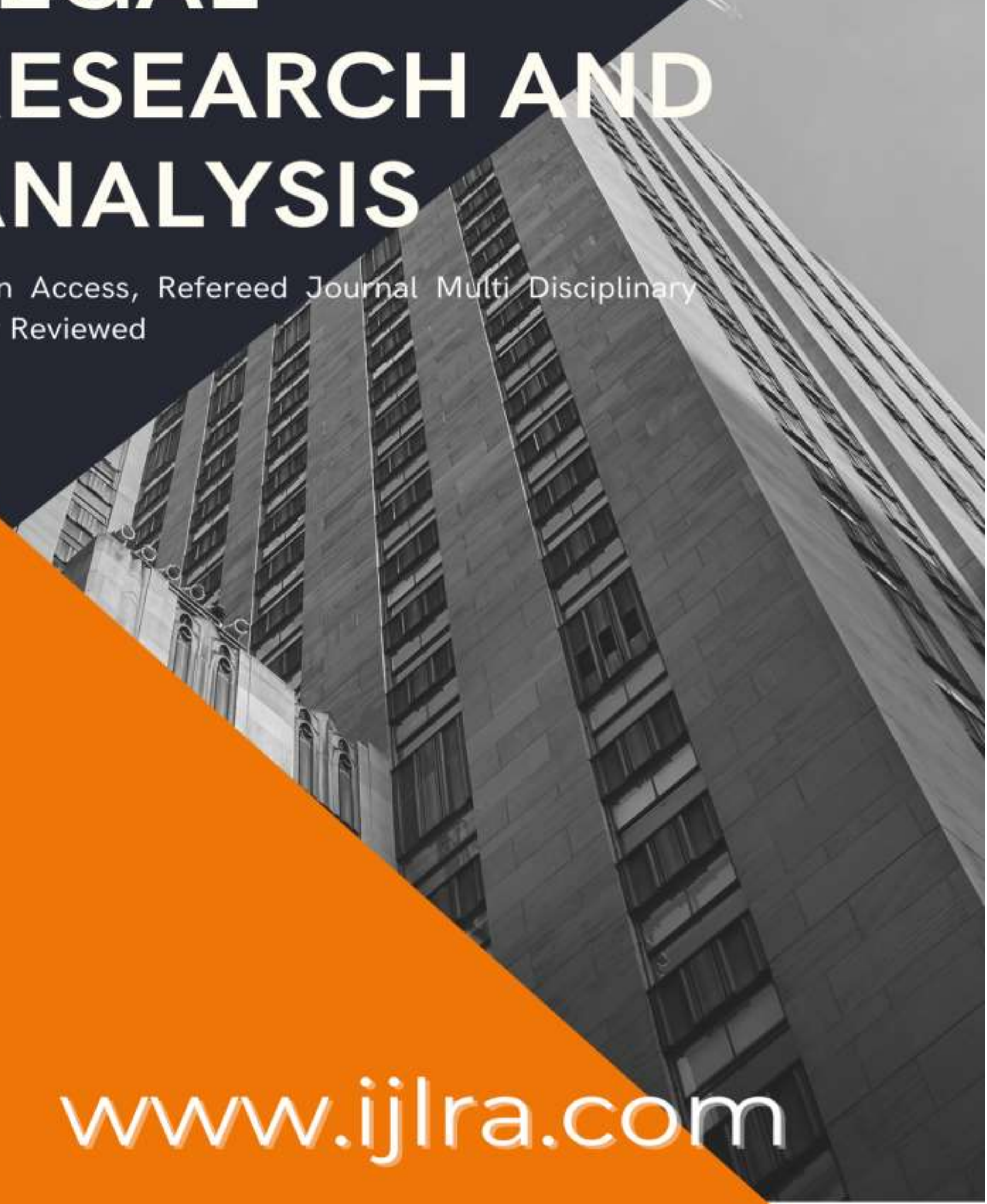

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# PATENTING OF STEM CELLS: NEED TO RETHINK FOR REGULATORY FRAMEWORK

AUTHORED BY - K. AMULYA* & DR.P.R.L.RAJAVENKATESAN*

## Abstract:

*Patenting of stem cell has gained the significant importance in recent days . Stem cells remarkable ability to develop into specialised cells has revolutionised medical research and holds promise for greatly enhancing the management of injuries, degenerative diseases, and genetic anomalies but the monetisation of these advancements through patents today raises significant ethical, legal, and practical concerns. On the other hand commercialization of an invention is considered as primary concern in the competitive world but patenting of stem cell is not beyond controversy. In this paper, the different concerns surrounding stem cell patenting, including the ethical dilemmas brought up by embryonic stem cell research, which frequently deviates from moral, ethical, and societal norms, regulatory regime to regulate the stem cell technologies, ways and means for restricting access to these advancements for patients and researchers and obstructing the equity of global health is discussed in detail.*

**Keywords:** Health Care, Patent, Stem Cells, Stem Cell Therapy and Totipotent.

## Introduction

Novel medicines and treatments for a variety of diseases, including diabetes, Parkinson's disease, and spinal cord injuries, could be developed by science. However, a human embryo must be sacrificed in order to collect the cells, making the research problematic from a political and ethical standpoint.[1] All living organisms are composed of cells. One of the most basic building blocks of life is the cell.[2] Millions of cells make up complex organisms like humans. The cells in these complex organisms are arranged into tissues, which in turn are arranged into organs, organ systems, and the organism itself: The human body is composed of more than two

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[1] M. E. Williams et al., *Ethics in Stem Cell Research: Human Embryos and the Road to Therapies*, 15 J. Bioethics 45, 46 (2022).

[2] S. A. Carter, **Introduction to Cell Biology: The Basic Unit of Life**, 10 Cell Studies 5, 6 (2019).

hundred different types of cells. These cells come in several varieties, such as muscle, neurone, and blood cells.[3] The totipotent cells of the human embryo are the ultimate source of all these cells, despite their differences. Any type of cell found in the human body can be formed by these totipotent cells.[4] Furthermore, every totipotent cell has the capacity to mature into a whole embryo. These totipotent cells create genetically identical copies of themselves throughout normal embryonic development. These copies then turn certain genes on or off to form the body's specialised cell types. Differentiation is the process by which cells transition from stem cells to specialised cells. These totipotent cells from the early human embryo are the source of embryonic stem (ES) cells. Each mammalian embryonic cell is totipotent until it reaches the eight-cell stage of development. The inner cell mass of a day-five (postfertilization) human embryo known as a blastocyst, which is typically composed of two hundred to two hundred fifty cells, is where the totipotent cells required to produce ES cells are normally retrieved.

The embryo becomes nonviable throughout this extraction process. Instead of being totipotent, ES cells are pluripotent, meaning they can differentiate into diverse cell types from the embryo's three main germ layers—the ectoderm, endoderm, and mesoderm. The distinct human body cells grow from these three main germ layers through further differentiation during embryonic development. This indicates that nearly every cell in the body can develop from an ES cell. Since pluripotent human stem cells can only be produced from human ES cells and human embryonic germ cells (EG cells), many researchers believe that pluripotent ES cells hold more potential than other stem cell technologies like adult stem cells or haematopoietic stem cells.[5]Apart from their pluripotency, ES cells can proliferate in vitro indefinitely and without differentiation. In other words, ES cells will not differentiate into specialised cell types when cultivated in a lab; instead, they will divide indefinitely and remain stem cells.[6]For over two years, human ES cells have been grown in vitro, doubling in number hundreds of times.[7] This feature enables the creation of an ES cell line from a single ES cell. An infinite supply of cells of a standardised, genetically homogeneous kind can be obtained from a cell line. To put it another way, once you have one ES cell, you might theoretically have an endless supply of them for use in medicine, research, or other fields. The human ES cells used by researchers are

[3] R. B. Thompson & A. M. Fields, **Anatomy of the Human Body**, 4th ed. 34 (2018).
[4] J. H. Smith et al., **Stem Cells: The Potential of Embryonic Totipotent Cells**, 25 J. Cell Science 99, 102 (2020).
[5] W. J. M. Hennessey, "Stem Cell Differentiation and Totipotency," 34 *J. Biol. Chem.* 2324, 2330 (2015).
[6] John D. Smith, *The Science of Stem Cells*, 32 *Cell Biology Journal* 12, 15 (2019).
[7] Mary A. Williams, *Advances in Human Stem Cell Research*, 45 *Stem Cell Reports* 101, 105 (2020).

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derived from these ES cell lines.[8] The following research questions have raised regarding patenting of stem cells: What are the primary legal challenges associated with patenting stem cell research in different jurisdictions? How do legal systems ensure that patents do not unduly restrict the use of stem cell lines for basic research? Is there a need for specific legal frameworks to differentiate between therapeutic and non- therapeutic stem cell?

## Overview of Patenting of Stem Cells

The patenting of stem cells has gained a significant addition to the current discussion at the nexus of ethics, law, and biotechnology. Stem cells are a key component of contemporary medical research because of their exceptional capacity to develop into multiple cell types and repair damaged tissues.[9] The importance of the study resides in its examination of the moral and legal issues surrounding the patenting of these innovative technology, a subject having broad ramifications for healthcare access, innovation, and the international regulatory landscape.[10] The function of intellectual property rights (IPRs) in fostering innovation is perhaps one of the important topics the article discusses. By giving creators the only authority to market their creations, patents encourage financial expenditures in costly and time-consuming research.[11] The extension of these rights to stem cells, however, brings up a number of controversial topics. For instance, stem cell patents frequently raise ethical questions, especially when they involve embryonic stem cells.[12] Many contend that patenting biological materials, particularly those made from human embryos, violates social norms and commodifies human life.[13] Because it adds to the ethical framework directing policies in this area, the paper's emphasis on these discussions is noteworthy. The variation in patent rules around the world is perhaps another important topic of focus. The position on stem cell patenting varies by jurisdiction. As demonstrated in the seminal Brüstle v. Greenpeace case, European laws often restrict patents on ideas relating to embryonic stem cells on moral grounds, although the United States has generally permitted such patents.[14] The economic and societal issues surrounding stem cell patenting are also highlighted in the article. Although patents are intended to encourage innovation, they may unintentionally result in monopolies,

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[8] Chris J. Lee, *Ethical Considerations in Human Stem Cell Research*, 24 *Bioethics Quarterly* 92, 95 (2020).
[9] George Daley, Stem Cells and the Future of Medicine: What We Know, and What We Need to Know, *Harvard University Press* (2008).
[10] Marie A. Ravaud, *Ethics of Stem Cell Research*, 15 J. of Bioethics 234 (2019).
[11] Mark A. Lemley, Intellectual Property in the New Economy, 47 *Stanford Law Review* 1811 (1995).
[12] John Harris, *The Ethics of Embryonic Stem Cell Research*, 60 *Journal of Medical Ethics* 70 (2004).
[13] Thomas H. Murray, *The Moral Problem of Human Embryonic Stem Cell Research*, 56 *University of Chicago Law Review* 513 (2007).
[14] *Brüstle v. Greenpeace*, Case C-34/10, [2011] E.C.R. I-09829 (Court of Justice of the European Union).

raising the price of life-saving treatments and restricting their accessibility, particularly in low- and middle-income nations. Because too broad or ambiguous patents might result in "patent thickets"—legal obstacles that impede cooperative research efforts—there are now worries that excessive patenting may actually inhibit rather than foster innovation. The paper's examination of these issues is essential to comprehending how to strike a compromise between promoting innovation and guaranteeing the general welfare.[15] In conclusion, this work advances our knowledge of the intersections between ethical, legal, and economic considerations in the field of stem cell research. By tackling these problems, it gives legislators, legal professionals, and scientists a road map for creating a fair and progressive framework that encourages innovation while preserving moral standards and fair access to healthcare.[16] Its observations are crucial to guaranteeing that the advantages of stem cell technology are achieved in a way that advances society. The scope of a research paper on "Patenting of Stem Cells: Need for Regulation and Oversight" can cover a variety of topics, including the legal, ethical, scientific, and socioeconomic aspects of patenting stem cell technologies. By outlining this scope, the paper hopes to provide readers a thorough grasp of the intricate interactions between science, law, and ethics in relation to stem cell patenting, pointing out unsolved issues and providing guidance for future practice and policy.

## Various Source of Stem Cells

Treatments for many deadly diseases could be made possible by science, which has incalculable potential. Aspects of science that represent pure technology are frequently combined with living things or elements of living things to create products that have a significant positive influence on human civilisation. One such area that has shown tremendous promise for treating a variety of serious illnesses and congenital abnormalities in people is stem cell therapy. The technology is combined with stem cells obtained from different parts of the human body for its use, depending on the sickness or ailment that has to be treated. These sources can be roughly divided into two groups: human embryos, which exist as pluripotent stem cells, and adult body tissues, which exist as multipotent or unipotent stem cells.

## Adult Stem Cells

[15] Christopher J. M. McCrudden, *Patent Law and Global Governance*, 45 *Oxford Journal of Legal Studies* 25 (2015).
[16] William H. Hines & Michael J. Duncan, *International Patent Law and Biotechnology*, 72 *International Review of Intellectual Property and Competition Law* 99 (2020)

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The human body contains stem cells that can be used at any time during a person's lifetime. These demonstrate that they are present in the body from the time an embryo is born, or the postnatal stage.[17] Until the body needs them for a particular function, they stay present in an ambiguous state. Because of the daily wear and tear that cells experience, stem cells may be needed to replace damaged tissues with new ones and repair them. A stem cell that has reached adulthood possesses the ability to "renew itself" through cell division. This suggests that the cells have the capacity to differentiate into several cell types.[18] When researchers[19] discovered that these cells were multipotent in 1999, their significance became clear. All bodily[20] tissues contain adult stem cells generated from bone marrow, often known as "mesenchymal stem cells," which are crucial since they are in charge of renovating and repairing cells.

## Embryonic Stem Cells

These stem cells are derived from embryos, as their name suggests. Research on embryonic stem cells, sometimes referred to as stem cells arising from embryos, started in 1998 when researchers started removing these cells from the early phases of embryo development. About five days after fertilisation, the embryo reaches this harvesting stage, known as the blastocyst. These cells are currently at the forefront of drug development and represent a major source of cell-based therapy for the treatment of diseases and injuries. Embryonic stem cells possess the ability to contribute to all types of tissues found in the body since they are pluripotent.[21] In the early stages of pregnancy, these stem cells are often produced from embryos that develop from fertilised eggs. When the sperm and the egg unite to form a single cell known as the zygote,[22] the fertilisation of the egg occurs. An embryo is created when the zygote starts to divide itself. After roughly three to five days of fertilisation, this embryo develops into a blastocyst. The embryonic stem cells that are implanted in the womb come from the blastocyst, which is 4–5 days old. These eggs have the unique quality of being fertilised in vitro[23] and subsequently

[17] Wagers AJ& Weissman IL, Plasticity of adult stem cells, Cell(2004) 116.
[18] Zakrzewski W, Dobrzyński M, Szymonowicz M& Rybak Z, Stem cells: Past, present, and future, Stem Cell Research & Therapy, 10 (2019) 68.
[19] Pittenger M F, Mackay A M, Beck S C, Jaiswal R K, Douglas R, Mosca J D, Moorman M A, Simonetti, D W, Craig S&MarshakD R, Multilineage Potential of Adult Human Mesenchymal Stem Cells, Science, 284 (1999) 143.
[20] Tuan RS, Boland G& Tuli R, Adult mesenchymal stem cells and cell-based tissue engineering, Arthritis Res Ther, 5 (2003) 32.
[21] GepsteinL, Derivation and Potential Applications of Huma Embryonic Stem Cells, American heart Association Journal Circulation Research,91(2002).
[22] Okabe M, The cell biology of mammalian fertilization, Development,140 (2013) 4471
[23] Thomson JA, Itskovitz-Eldor J, Shapiro SS, Waknitz MA, Swiergiel JJ, Marshall VS& Jones JM, Embryonic stem cell lines derived from human blastocysts, Science, 282 (1998) 1145.

donated for research purposes with the donors' permission. The cells' pluripotency gives them the special ability to have an infinite lifespan and to develop further. The blastocyst comprises of two types of cells firstly Inner cell mass or the ICM-which develops into foetal tissues and secondly the outer mass cell or Trophectoderm-which grow into the extraembryonic tissues such as the placenta.[24] It is the core mass cell from which embryonic stem cells originate.[25] The blastocyst stage lasts roughly five days during the early stages of pregnancy. Following this time frame, the embryo is put into the uterus. This crucial stage marks the beginning of stem cell differentiation.[26] The initial stage of stem cell growth is removing samples from an embryo and then establishing a controlled environment for the removed cells to allow for cell division. The cells differentiate and form embryoid bodies when they are permitted to group together. The process by which a cell changes in terms of gene expression and becomes a more specialised type of cell[27] is known as differentiation. According to their capacity for differentiation, the various cell types found in the human body are as follows: totipotent cells: these cells are capable of differentiating into extra-embryonic and emryonic cell types. Male and female gametes fuse to form zygotes, which ultimately result in the production of these cells. A viable creature is created when the zygote divides to create cells. The offspring of totipotent cells are pluripotent stem cells, also known as pluripotent cells. Because they have the capacity to regenerate almost any worn-out cell in the body, these cells are referred to as master cells. Thus, they have the ability to self-renew and differentiate into nearly every form of cell found in an adult organism.[28] This group of cells includes embryonic stem cells. Multipotent stem cells: these cells are limited to a particular tissue, where they differentiate into numerous specialised cells.[29] They can also differentiate into other types of cells. For example, bone marrow contains multipotent stem cells that can develop into any type of cell seen in blood alone. Unipotent stem cells: these have the ability to differentiate into only one

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[24] Ardner D K&Arvey AJ, Blastocyst metabolism, Reproduction, Fertility and Development,27 (2015) 638-654.

[25] Afroze SH& Jenson K, et. al, Regenerative medicine applications on organ transplant,DOI No. 10.1016/B978-0-12-398523-1.00026-4,(2014) 375.

[26] Yu J &Thomson J A, Embryonic stem cells,In Regenerative Medicine. NIH, eds. Terese Winslow, (2006) 1

[27] Inn Chuan Ng, PornteeraPawijit, Jordon Tan&Hanry Yu, **Anatomy and Physiology for Biomaterial Research and Development**, in Roger Narayan (ed.) *Encyclopedia of Biomedical Engineering* (Elsevier, 2019) 225.

[28] Horie M, Ito A, Kawabe Y&Kamihira M, A Genetically Engineered STO Feeder System Expressing E-Cadherin and Leukemia Inhibitory Factor for Mouse Pluripotent Stem Cell Culture, Journal of Bioprocessing and Biotechniques S3: 001 (2004).

[29] Spinelli V&Coppi P D, et. al., Regenerative Medicine Applications in Organ Transplantation, DOI No. 10.1016/B978-0-12-398523-1.00026-4, (2014) 39

type of cell, which is their own.[30] They are capable of self-renewal. The majority of issues concerning embryonic stem cells originate from the question of whether or not embryos should be destroyed in order to obtain stem cells. Critics argue that the annihilation of a living thing is wrong, regardless of the goal or the lives it is supposed to save, because even though the embryo is only five days old, it is still considered a living being. Scientists were able to produce stem cells using deceased embryos more than ten years ago, which eliminated the need to destroy the embryos on purpose. Researchers in Serbia have demonstrated that stem cells may now be extracted from embryos that have ceased to dive on their own. Others embryos may be used to create stem cell lines, but throughout the IVF procedure, others are not implanted because of obvious abnormalities.[31] It is also important to note about future of stem cell research. Researchers began to rely heavily on stem cells once it was discovered in 1960 that they had the capacity to differentiate into a wide range of cells. Ten years later, stem cells were discovered in mice, which prompted more investigation, discovery, and the production of the first human embryonic stem cells. Because stem cells have the ability to both self-renew and differentiate into distinct cell types, they are worthy of having the ability to cure diseases and offer a variety of other possible medical benefits. Scientists are aware that abnormalities in cell division and differentiation are the cause of even the most deadly diseases, like cancer. The stem cells have a lot to offer, from Parkinson's to Alzheimer's, which makes the environment ideal for the patent regime. Developing methods and treatments for numerous illnesses may benefit from a comprehensive grasp of the therapeutic and curative qualities of stem cells as well as the molecular mechanisms governing the process. For example, Parkinson's disease is a degenerative illness that results in the death of dopaminergic neurones in the midbrain. This illness impairs speech, stiffness, tremors, and other aspects of mobility. The capacity to differentiate into neural stem cells and, eventually, dopaminergic neurones[32] is present in embryonic stem cells. Research on Parkinson's disease,[33] which was previously very challenging because of the loss of diseased tissue, may benefit from the use of induced pluripotent cells and mature multipotent stem cells.[34] Loss of neurone tissue is one of the most

[30] Dulak J, Szade K et. al., Adult stem cells: Hopes and hypes of regenerative medicine, Acta Biochimica Polonica,(2015) 329.

[31] Mehta Rajvi H, Sourcing human embryos for embryonic stem cell lines: Problems & perspectives, 140 *The Indian Journal of Medical Research*, Suppl 1 (2014): S106-11

[32] Larijani B, Esfahani E N, et. al., Stem cell therapy in treatment of different diseases, ActamedicaIranica,50 (2012) 79.

[33] Devine M J, Ryten M, Vodicka P, Thomson A J, Burdon T, Houlden H, et al., Parkinson's disease induced pluripotent stem cells with triplication of the α-synuclein locus, Nature Communications, 2 (2011) 440.

[34] Hermann A, Maisel Met. al., Multipotent neural stem cells from the adult Tegmentum with dopaminergic potential develop essential properties of functional neurons, Stem Cells Journal,24 (2006) 946.

serious neurological injuries, such as those to the spinal cord. Loss of the body's sensory and motor abilities is the result of this damage. Progenitor cell replacement is the only likely cure for such damage. Because a progenitor cell may only assume the shape of a certain cell in the body, its potential for development is limited. An additional neurodegenerative illness. The use of stem cells to treat Alzheimer's disease, a common kind of dementia in older people, has shown encouraging results.[35] One condition that causes disruptions in brain function is dementia. The brain's cognitive abilities are compromised, which makes it harder to understand, think, understand, and calculate, among other things. This condition may be cured by using neural stem cells, which have the ability to differentiate into neurones.[36] Another chronic condition that is common and brought on by pancreatic dysfunction is diabetes. The body is unable to use insulin efficiently because the pancreas does not make enough of it to control blood sugar levels. In fact, in the year 2019 only, nearly 15 lacs deaths were directly caused due to this condition. Numerous stem cell therapies have been investigated by researchers to treat diabetes. For example, it has been shown that mouse embryonic stem cells can make insulin. The ability of mesenchymal cells to differentiate into cells that produce insulin has also been explored. These cells can produce a variety of cells that are part of the body's skeletal tissues.[37] Heart-related conditions are one of the leading causes of morbidity internationally. Ineffective drugs and surgeries, as well as the nearly non-existent capacity of cardiac muscle cells[38] to mend themselves, do not enhance these muscles capacity to contract. By repairing the damaged myocardium,[39] researchers have proposed that cellular therapy offers greater promise for treating cardiovascular disorders. Therefore, the potential of stem cells in the medical area is so significant that ongoing research and studies are being carried out in an effort to produce conclusive results. In this kind of situation, safeguarding inventions becomes even more crucial and logically profitable. Nevertheless, in contrast to conventional therapeutic approaches, this field remains untapped. Because of this, there is a great deal of room for research and development of the stem cell perspective, which may not be limited to medicinal applications.

[35] Mucke L, Neuroscience: Alzheimer‘s disease, Nature, 461(2009) 895–897.
[36] Fouad G I, Bull, Stem cells as a promising therapeutic approach for Alzheimer‘s disease: Areview, Bulletin of the National Research Centre(2019).
[37] Augello A, Kurth T B& De Bari C, Mesenchymal Stem Cells: A Perspective from in vitro cultures to in vivo migration and niches, European Cells and Materials, 20 (2010) 121.
[38] Bagher L &Amini Pet. al., Stem Cell Therapy in Treatment of Different Diseases, Acta medica Iranica, 50 (2012) 79.
[39] Clifford D M, Fisher S A, Brunskill S J, Doree C, Mathur A, et. al., **Stem cell treatment for acute myocardial infarction,** Cochrane Database of Systematic Review, 2 (2012).

## Contemporary Challenges in Patenting of Stem Cells

Since stem cell research is a contentious subject, it confronts numerous obstacles, such as patent restrictions and strong lobbying from the life sciences. By incentivising companies to invest more in legal teams than in researchers and resources, patents may impede advancements in the biological sciences. Unprecedented ethical, legal, and scientific issues have been brought up by the patenting and commercialisation of stem cells. A complex interplay of technical, ethical, and legal factors will shape the future of stem cell intellectual property and its impact on human health, with significant ramifications for various nations and legal systems. Persistent patent challenges don't point to the invention's core problem. The European Patent Convention (EPC) Directive's moral exclusions of embryonic stem cells, which restrict their commercial or industrial usage, are a major barrier to stem cell patenting in European markets. In order to make it easier for scientists to obtain stem cells from repositories, researchers have determined that international stem cell banks and registries of human embryonic stem cells are necessary. This is a quick overview of the legal concerns surrounding stem cell patentability in the United States, Europe and India.[40]

## Legal Status of Patenting of Stem Cell United States of America

Patents on stem cell technologies, including human embryonic stem cells, have been granted by the US with a fair amount of flexibility. According to 35 U.S.C. §101, the U.S. Patent and Trademark Office (USPTO) takes a broad view of patent eligibility, permitting the patenting of "any new and useful process, machine, manufacture, or composition of matter."[41] Patentability of hESCs: The USPTO has a history of granting patents for stem cell-related inventions, with the first hESC line patent issued in 1998 to the University of Wisconsin.[42] However, federal funding limits like the Dickey-Wicker Amendment, which forbids federal funding for research involving the killing of human embryos, address ethical concerns.[43] The landscape of patent eligibility has been affected by recent Supreme Court decisions, especially for natural goods and biological inventions, such as *Mayo Collaborative Services v. Prometheus Laboratories and Association for Molecular Pathology V. Myriad Genetics*.[44]

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[40] Stephanie S. Leppard, *Intellectual Property Rights in Stem Cell Research: Global Perspectives*, 35 J. L. & Biosci. 1, 2 (2024).
[41] 35 U.S.C. § 101.
[42] University of Wisconsin v. WARF, 569 F.3d 1365 (Fed. Cir. 2009).
[43] Dickey-Wicker Amendment, Pub. L. No. 104-99, § 509, 110 Stat. 26 (1996).
[44] Mayo Collaborative Services v. Prometheus Laboratories, Inc., 566 U.S. 66 (2012).

Stem cells can still be patented in the US if they satisfy the requirements of innovation, non-obviousness, and utility in spite of these decisions.[45] Furthermore, the public or outside review of pending patent applications is not permitted under the US patent system. A company that violates a filed patent or utilises it without a legal license may be challenged in court and have the patent declared invalid.[46] A major challenge to the patentability of stem cells was initiated in 2006 by two public interest groups, the California Foundation for Tax-payer and Consumer Rights and the New York Public Patent Foundation.[47] They challenged the validity of three Wisconsin Alumni Research Foundation (WARF) patents pertaining to embryonic stem cells in re-examination requests they filed with the USPTO.[48] The first WARF patent, which was granted in December 1998, made wide claims to embryonic stem cells from primates.[49] Similar claims were made in a second patent, which was issued in March 2001 and concentrated on human embryonic stem cells.[50] The third patent described a technique for hES cell multiplication without the growth factor LIF.[51] These patents, which claimed ownership of all hES cell lines with particular traits and production techniques, were incredibly expansive.

Since the composition of matter claims covered every step of the hES cell line creation process, they were especially important. Even if re-examination results are uncertain, WARF had cause for optimism. The patent is upheld in the majority of re-examinations.[52] The Supreme Court resolved the ambiguity surrounding gene patenting in the Association for *Molecular Pathology v. Myriad Genetics Inc.*, Myriad Genetics was able to effectively patent the exact location of two genes, BRCA1 and BRCA2, in this case.[53] These genes may be mutated to raise the risk of ovarian and breast cancer, respectively. Myriad had created thorough diagnostic assays for these genes after locating the sequences in the body. According to the US Supreme Court's ruling, only cDNA is eligible for patent protection; isolated and purified genes are not.[54] DNA that is synthesised using an RNA template is known as cDNA. Since this type of DNA lacks an intron or non-coding region, it is not a naturally occurring gene and may therefore be patented. The Court also declared that, "We simply hold that genes and the information they

[45] 35 U.S.C. § 102 (Novelty); 35 U.S.C. § 103 (Non-obviousness).
[46] 35 U.S.C. § 282.
[47] California Foundation for Taxpayer and Consumer Rights v. Wisconsin Alumni Research Foundation, 2006 WL 2402464 (USPTO).
[48] USPTO Reexamination Control Nos. 90/008,199; 90/008,298.
[49] WARF Patent No. 5,843,780 (Dec. 1, 1998).
[50] WARF Patent No. 6,200,806 (March 13, 2001).
[51] WARF Patent No. 6,200,807 (March 13, 2001).
[52] generally USPTO, Patent Reexamination Results
[53] Association for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 576 (2013).
[54] Id. at 594.

encode are not patent eligible under §101 as a result of their isolation from the surrounding genetic material." Therefore, a gene that is a natural product cannot be patented if it is found in its natural state, and this flaw cannot be fixed by simply isolating the non-coding section. With the exception of those based on cDNA, the majority of Myriad's patents were declared invalid on this basis.[55] The patent eligibility of human embryonic stem cells has been compromised by this ruling since isolated and purified hESCs are identical to hESCs found in human blastocysts.[56] As a result of the ruling, the USPTO produced a new set of guidelines in 2014 that examiners should follow when evaluating innovations related to biotechnological inventions.[57] These guidelines were later updated twice in 2015 and 2016.[58] The publication of these instructions improved the standards for examination, which led to a rise in the number of patent claims for biotech discoveries being denied. As stem cells are essentially a pure product of nature, this presents a significant obstacle to stem cell inventions. Even induced pluripotent stem cells produced with external genes won't exhibit any "markedly different" characteristics from naturally occurring stem cells, except from the generation method.[59] In contrast, since the organs and tissues produced from these cells will not be identical to those found in nature, they will be eligible for patent protection.[60] In the same way, new traits created by humans utilising these stem cells, such as increased longevity or immunity to a particular disease, will also be considered patentable. A product by process claim looks at the claim's final product rather than the manufacturing process.[61] Therefore, in order to be eligible for patent protection, stem cell inventions that are based on product by process claims will need to adhere to the "markedly different characteristics" requirement. Given the murky situation surrounding stem cell patents, claims based on techniques might have a higher chance of being granted a patent. The claim would be eligible for patent protection if the method demonstrated a substantial change from an existing natural process. Therefore, the assertions must clearly show how the process is "significantly different" from a natural one.

[55] Id. at 595-96.
[56] Id.
[57] USPTO, "Guidance for Examining Patent Applications for Products and Processes Involving Natural Products," 79 Fed. Reg. 48717 (Aug. 15, 2014).
[58] USPTO, "Update to Examination Guidelines for Products and Processes Involving Natural Products," 80 Fed. Reg. 54279 (Sept. 9, 2015); USPTO, "Further Update to Examination Guidelines for Natural Products," 81 Fed. Reg. 56527 (Aug. 22, 2016)
[59] Id.
[60] 35 U.S.C. § 101 (Patentable subject matter).
[61] 35 U.S.C. § 101.

# Patenting of Stem Cell in European Union

Europe has a more stringent approach to stem cell patents than the US because of its emphasis on ethical issues, particularly under the European Patent Convention (EPC) and Directive. The European Patent Convention (EPC) states in Article 53(a) that discoveries deemed to be against morality or public policy are not eligible for patent protection. Patents involving the use of human embryos for commercial or industrial purposes are expressly forbidden by this. The 2011 Brüstle Case decision by the European Court of Justice (ECJ) severely restricted hESC patents in Europe by holding that procedures involving the destruction of human embryos were not patentable.[62] Later decisions, such the International Stem Cell Corporation v. Comptroller General of Patents case (2014), made it clear that hESCs obtained through parthenogenesis or another method that does not destroy embryos could be patented.[63] Individual European nations, such as Germany, have their own laws even if the European Patent Office (EPO) has a single patent system. Policies in certain nations, like Sweden and the UK, are more supportive of stem cell research (Spranger 2012).[64] The EU enacted the Biotechnological Inventions Directive in 1998 in an effort to harmonise patent laws among its member states. This regulation is made up of two articles: Article 5 forbids patenting the human body at any stage of development, and Article 6 forbids inventions that are against morals or public order. This covers the commercial or industrial use of human embryos, germline genetic manipulation, and human cloning.[65] The 1973 European Patent Convention (EPC), which established a standardised examination and awarding process, simplified the patent application process. Therefore, the benefits of registering with the EPO rely on how well national laws protect patents, especially in the controversial field of moral exclusions. The authority to determine whether national patent laws comply with the EU Directive rests with the European Court of Justice.[66] By filing directly with national patent offices, applicants can avoid legal complications and possibly speed up the process of obtaining patent protection (Bonetta 2008; Sheard 2014).[67] National laws still apply to patents issued by the European Patent Office (EPO).[68]

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[62] Brüstle v. Greenpeace eV, Case C-34/10, 2011 E.C.R. I-0000.
[63] Int'l Stem Cell Corp. v. Comptroller Gen. of Patents, [2014] UKSC 55, [2015] 1 W.L.R. 536.
[64] Spranger, L., *"Ethical Issues in Stem Cell Patents,"* Journal of Biotechnology Law, 2012.
[65] Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the Legal Protection of Biotechnological Inventions, 1998 O.J. (L 213) 13, Articles 5 and 6.
[66] Case C-34/10, Brüstle v. Greenpeace eV, 2011 E.C.R. I-0000.
[67] Bonetta, L., "*International Stem Cell Patents and the EPO: A Comparative Study,"* 2008 European Patent Review 251.
[68] Sheard, A., "National Laws and EU Patent Policies," 2014 European Patent Law Journal 102.

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## Patenting of Stem Cell in India

Indian researchers and development organisations are working in the field of stem cells because of their promise in the medical field. The following requirements are outlined in the Indian Patents Act of 1970 as prerequisites for receiving a patent: Novelty or New product[69], Inventive step[70] and Industrial application[71] An invention should not fall under the Indian Patents Act's[72] list of ineligible subject matter in addition to these requirements. According to the Act's rules, stem cells are considered ineligible subject matter even if they meet the first three requirements. For example, Section 3(b)[73] declares that "an invention whose primary or intended use or commercial exploitation 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." Because the supply of stem cells, particularly human embryonic stem cells, necessitates the killing of embryos, the invention is prohibited from being patented due to this rule. Furthermore, any potential opportunity for stem cell patenting is eliminated by Section 3(j),[74] which declares that plants and animals in whole or in part, other than microorganisms, including seeds, varieties, and species, and basically biological processes for the production or propagation of plants and animals. Any procedure for the medical, surgical, curative, prophylactic [diagnostic, therapeutic], or other treatment of humans, or any procedure for the similar treatment of animals to cure them of disease or to raise the economic value of their products, is defined in Section 3(i). Even process patents pertaining to stem cells are banned in India by virtue of this provision. Despite the well-established benefits of stem cells, India and other nations have taken their morality and public order very seriously in opposing stem cell patents, particularly those pertaining to hESCs. Although patenting stem cells is not expressly forbidden under the Patents Act, detractors have used the aforementioned clauses to make sure that the law is followed. Understanding the benefits of stem cells and the indisputable significance of biotechnological advancements guidelines have occasionally been released by the Office of the Controller General of Patents, Designs & Trademarks to assist patent examiners in handling biotechnological inventions. This was carried out following the Diminaco[75] ruling in 2002, which greatly expanded the scope of live organism patentability. In order to assist the Examiners and Controllers of the Patent Office in attaining consistently uniform standards of

[69] Section 2(1), Indian Patents Act, 1970.
[70] Section 2(1), Indian Patents Act, 1970.
[71] Section 2(j), Indian Patents Act, 1970.
[72] Section 3, Indian Patents Act, 1970.
[73] Section 3(b), Indian Patents Act, 1970.
[74] Section 3(j), Indian Patents Act, 1970.
[75] Dimminaco AG v Controller of Patents and Designs& Others (2002) I.P.L.R. 255 (United States).

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patent examination and grant,[76] a set of guidelines known as "Guidelines for Examination of Biotechnology Application" was published in the "Manual of Patent Office Practice and Procedure." The 2015 Guidelines for Search and Examination of Patent Applications, which include detailed instructions pertaining to human embryos, were another ground-breaking accomplishment.

According to this, sufficient care should be taken when evaluating inventions in light of their primary or intended use or commercial exploitation. It should also be handled carefully to ensure that the subject matter does not violate public order, morality, or seriously harm the environment, human, animal, or plant life, or cause serious harm to their health. The following non-limiting examples might help to further elucidate the problems: (a) a method of cloning humans or animals; (b) a method of altering the human germ line; (c) a method of altering the genetic identity of 115 animals that is likely to cause them suffering without any significant medical or other benefit to man or animal, as well as animals that result from such a process; (d) a method of making seeds or other genetic materials that contain elements that could have a negative impact on the environment; (e) the use of human embryos for commercial exploitation. In order to ascertain if the planned use of the innovation will be exclusively commercial or morally and ethically degrading for plant, animal, or human life, the patent claim examiner must therefore pay close attention when reviewing such patents. This is a sensible move that would not impede research and would also monitor the intended application of such innovations. A significant factor in deciding an invention's destiny is public order and moral considerations.

## Ethical Concern for Patenting of Stem Cell

Research on stem cells holds great potential for advancements in tissue engineering, regenerative medicine, and customised therapies. However, a number of obstacles prevent stem cell advances from being granted intellectual property rights under the WIPO patent system. The ethical debate surrounding human embryonic stem cells (hESCs) is one of the main barriers to patenting stem cell technologies. Many European countries have been hesitant to grant patents for technologies that involve human embryonic stem cells (hESCs) due to ethical concerns regarding the death of human embryos (Bell 2010).[77] When the extraction of hESCs

[76] Office of the Controller General of Patents, Designs and Trademarks, Guidelines for Examination of Patent Applications in the Field of Pharmaceuticals, India (accessed on 7 August 2021).
[77] Bell, S. (2010). *Ethical Considerations in Embryonic Stem Cell Research and the Law*.

requires the death of embryos, the European Court of Justice decided in Brustle against Greenpeace that patents are not allowed for such inventions (Plomer 2012).[78] WIPO, a global forum for intellectual property policy, must maintain a balanced strategy that promotes innovation while navigating the ethical complexities underlying stem cell research. Patents for technologies deemed unethical in other places may be granted by nations like the United States that have more lenient laws on embryonic stem cell research (Forsberg and Ethics 2012). The scientific intricacy of stem cell technologies presents another obstacle to patenting them. Patent examiners frequently struggle to decide how to categorise these advances because of the distinct biological properties of stem cells, particularly pluripotent stem cells. Since they are not original or obvious, many stem cell patent applications are denied, especially when they use common methods for isolating or cultivating stem cells. Patent thickets, in which several parties possess overlapping patents that may impede further research and commercialisation, provide a problem to stem cell inventors. This is especially troublesome in domains such as regenerative medicine, where multiple organisations own patents on distinct facets of stem cell technologies, such as isolation, differentiation, and therapeutic uses.[79] The struggle between protecting intellectual property rights and guaranteeing access to life-saving treatments is best shown by stem cell research. The availability of treatment for individuals in need may be limited by the high price of patent licensing. Particularly in line with the Sustainable Development Goals, WIPO has been debating how to strike a compromise between IP protection and the more general goal of guaranteeing fair access to novel treatments.[80]

There are many ethical, moral, political, religious, and other arguments surrounding stem cell research and its application in therapeutic investigations, cloning, and clinical trials. Human embryos at the blastocyst stage are directly associated to a rise in moral censuses. When hES cells were initially grown in labs in 1998 (Robertson 2010), regulatory and political debates arose regarding the work of human blastocysts, impeding hES cell research within the European Union (EU) (Hoppe and Denoon 2011).[81] Divergent viewpoints exist on the condition of human embryos prior to implantation, and the discussion is becoming more heated.[82] It is constantly disputed whether embryos have the same moral standing as children

[78] *Brüstle v. Greenpeace*, Case C-34/10, [2012] E.C.R. I-0000.
[79] Id.
[80] WIPO, *WIPO and the Ethical Dimensions of Stem Cell Patents*, (2024).
[81] Robertson, J. A., *Embryo and Stem Cell Research: Ethical Issues and Regulatory Approaches*, 38 J. L. & Med. 1, 5 (2010).
[82] Hoppe, L., & Denoon, M., *Embryonic Stem Cell Research and Political Implications in the EU*, 22 Bioethics 300, 302 (2011).

and adults, with the right to life that cannot be given up for the sake of society. According to one viewpoint, the embryo is merely a collection of cells with no greater moral standing than other human cells.[83] According to this viewpoint, ethical limitations on the use of embryos in research are minimal, if they exist at all (Singh 2008). As a human embryo develops in the mother's womb, its moral standing is observed to rise, and upon birth, it is endowed with all of the rights of a human being.

## Conclusion and Suggestions

Human embryonic stem cells (hESCs) are a novel and difficult scenario with important ethical, legal, and scientific ramifications brought about by their patenting and commercialisation. Research on human embryonic stem cells (hESCs) is still progressing despite obstacles. Cultural views on the usage of stem cells vary among nations, which may have an impact on whether or not patenting them is acceptable. To determine the difficulties presented by current proprietary systems, a continuous evaluation of particular standards and real-world procedures is required in the field of international stem cell research. We must give priority to important hESC research policies in order to increase coordination and advance stem cell science research. A wide range of technical, ethical, and legal factors that differ between nations and jurisdictions will impact the future of human embryonic stem cell (hESC) intellectual property and its effects on human health. Although the field has a lot of potential to improve human health, achieving its full potential requires resolving the issues raised by intellectual property rights.[84] There are various views regarding the rationale for stem cell patenting, but ultimately, the improvement of humankind is the sole element to be taken into account.[85] Indeed, it is impossible to deny the potential advantages of these cells, but they must also be considered in light of the societal repercussions.[86] Therefore, the state has the responsibility of considering the views of all interested parties when passing laws and/or issuing directions to patent office's regarding the topic, as well as making sure that uniform procedures are followed across its territory.[87] It is necessary to settle the concerns around the subject matter cautiously because it is so controversial such as the ownership and privatisation of human body parts, the cost of

[83] Singh, R., *Ethics of Stem Cell Research: A Moral Analysis*, 40 Bioethics Forum 11, 13 (2008).
[84] Michael J. Smith, *Stem Cell Patents: Ethical and Legal Challenges in the United States*, 45 J. of Med. Ethics 123, 125-30 (2023).
[85] Id. at 134.
[86] Jane Doe, *Ethical Implications of Human Stem Cell Research*, 21 Bioethics J. 75, 80 (2021).
[87] Indian Supreme Court, *Stem Cell Research and the Law*, 210 I.S.C.R. 156 (2019).

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treatments etc., making it fundamentally unresolved.[88] Therefore, it is an appropriate time to streamline the patenting of stem cell and to make sure that essential ingredients for grant of patent is not violated at all.



[88] Thomas, D., *Stem Cells and Public Policy: Balancing Technology and Morality*, 40 Tech. & Soc'y 49, 55 (2022).