

PATENTABILITY OF HUMAN EMBRYONIC STEM CELLS IN INDIA

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Abstract - The hESC research with recent developments has become one of the most desirable research fields for the scientist. The reason behind such an approach is basically the great potential to treat and cure the human race of very incurable diseases. Countries around the world have amended their policies with regards to stem cells in such a way as to enhance the advantage as the stem cell market is a trillion-dollar market. The research procedure involving patentable invention is time-consuming and requires many expenses, so the investor is always keener to know if they will get any monetary benefit. Though the medical field promises about importance of stem cell and biotechnological research, there are concerns in some countries, such as India, about potential policy implications that would affect the patenting innovations in this industry. As India lacks a coherent legislative policy regarding stem cell patenting, it is creating more confusion for research in stem cell research. Often, researchers do not want to be involved in the said research because India lacks any specific laws in said fields apart from so-called guidelines provided in 2017 with an amendment to Drug and Cosmetic Act in 2019. Patent laws play a vital role in industrial advancement, thus helping a country's economy. To enter the race of development, countries worldwide have developed their patent laws so that they achieve maximum benefits out of it. In India, with patent laws, moral, cultural and religious beliefs also play a vital role in granting a patent, specifically in the Human Embryonic Stem Cell patent. The Article discusses topics that a researcher must be familiar with when discussing patentability issues. A few of these topics include the morality debate, stem cell and biotechnological research, and Stem cell research's patentability. Additionally, this Article identifies the discrepancies between the laws governing stem cell research within India.


Keywords: *Human Embryonic Stem Cells, Patent, Intellectual property rights, Biotechnology research*

INTRODUCTION

A new idea or new information can easily be kept secret unless, the person who has it wants to seek some benefit out of it. When such ideas or information are shared with other persons, chances are there, that such can be misused or maybe that person start misappropriating the same as his own. The Intellectual Property (hereinafter mentioned as I.P.) law is a resource for such people, who not only want to protect such ideas but also have some commercial opportunities with some cost for defined period.³

Indian culture is vibrant which has got lot of different traditions, a unique lifestyle and a dynamic economy which indeed is a powerhouse of innovative ideas and knowledge which leads to intellectual property. Such uniqueness of knowledge needs a great protection as eventually such ideas will not only help inventors but also the people in future. The Indian Patent Office

³ Devaiah, V. H. (2010). Impact of bioethics on patentability of inventions. Indian Journal of Medical Ethics, 7(1), 14–18. Retrieved from <https://pubmed.ncbi.nlm.nih.gov/20166289/> (Last Accessed October 20, 2020)


 (hereinafter mentioned as IPO) is one of the most important offices when it comes to protection of patents which is one of the IP rights apart from trademark, copyright etc.⁴

Patent laws play a very vital role when it comes to industrial advancement, thus helping the growth of economy of a country. To get into the race of development many countries have developed their patent laws in such a way that they achieve maximum benefits out of it. In India with patent laws, the moral, cultural and religious believes also play a vital role for granting patent specifically in Human Embryonic Stem Cell (hereinafter mentioned as hESC) patent.⁵

The use of technology actually helps us to understand if its results are going to be good or bad. As such it doesn't hold any character of its own but how we use it determines its character. He Jiankui, a Chinese scientist, recently made a groundbreaking research when he claimed that he have made the world's first babies which were genetically edited who were females and they have been made to naturally resistant to Human Immunodeficiency Virus(hereinafter mentioned as HIV) by removing a CCR5 from their embryos using technique named as CRISPR Cas9. He was condemned a lot for this research to the extent that one of the scientists, Dr Kiran Musunuru, a University of Pennsylvania gene editing expert and editor of genetics Journal said that "It is unconscionable..... An experiment on human beings that is not morally or ethically defensible." Thus, research was given lesser importance when morality was hampered.⁶

The patent laws at international level have lot of uncertainty when it comes to application and its relationship with morality and ethics. Basically morality and ethics always come and picture whenever hESC patents are concerned. Patent laws in US are based on the principle that patent first, ask questions later. So morality or ethics as such does not play any role when it comes to granting patents. In the USA, the patent is granted for any such researches which are novel, useful and has industrial application. This doesn't mean that they allow all the researches but do have some limitation when the research is in moral or may harm to public at large. That is the reason human cloning is banned in USA but when it comes to research on hESC they allowed the research on existing stem cell line.⁷

In the simplest words, the stem cell is an immature cell which can differentiate into any possible cell in a human body. It is categorized into adult stem cells, embryonic stem cells and induced pluripotent stem cells based on its source. The Adult Stem cells (hereinafter mentioned as ASC) are found in adult tissues which maintain and repair the same. ASC have limited number of possible pathways to differentiate into cell types. Whereas the hESC derived from the inner cell mass (hereinafter mentioned as ICM) of pre-implantation embryos, embryonic germ cells and fetal germ cells can differentiate into many cell types. While the adult stem cells are only multipotent, hESC comes under the category of either being totipotent or pluripotent depending on the stage of harvesting the stem cells.⁸ The hESC typically show very little

⁴ Gupta, R. (2018, December). Morality and Ethics Embracing Biotechnology Patents. 41–47. Retrieved from http://proceeding.conferenceworld.in/Pune_RISE-18-Conference/TJP5Q3leP729.pdf (Last Accessed January 14,2021)

⁵ Halliburton, M. (2017). India and the Patent Wars: Pharmaceuticals in the New Intellectual Property Regime (The Culture and Politics of Health Care Work) (Illustrated ed.). ILR Press.

⁶ Gupta, R. (2018, December). Morality And Ethics Embracing Biotechnology Patents. 41–47. Retrieved from http://proceeding.conferenceworld.in/Pune_RISE-18-Conference/TJP5Q3leP729.pdf (Last Accessed January 14,2021)

⁷ Halliburton, M. (2017). India and the Patent Wars: Pharmaceuticals in the New Intellectual Property Regime (The Culture and Politics of Health Care Work) (Illustrated ed.). ILR Press.

⁸ Singh, R., & Singh, K. (2018). Biological patent and patentability. Integrated Journal of Social Sciences, 5(2), 35-40. Retrieved from <http://www.pubs.iscience.in/journal/index.php/ijss/article/view/859> (Last Accessed January 13,2021)

differentiation, thus are considered to have enormous therapeutic potential than ASC.⁹ Owing to this property, hESC can form all the 220 types of cell in the human body.¹⁰

Unlike the USA, India does have section 3(b) under the Patent (Amendment) Act, 2005 which we specifically referred as a morality clause. With this clause we also have guidelines provided by office of the Controller General of Patents, Designs and Trademarks in March 2013 which provide few examples of such research under biotechnology which are not patentable as they are against public morality one of them being extraction of hESC from embryos and using the same for research.¹¹

The nature of biotechnology industries has certainly made them important innovative factors as they are much diversified. Modern IP laws have failed to identify hESC patents as an important form but still they have made a rapid progress in last three decades which made different development and scientific world. Though as stated earlier that, they have made progress but still morality on the other hand has caused a lot of hindrance to such research eventually stopping the growth and making the economy stagnant. It's need of an hour to have this confusion sorted out and give some proper rules and regulations for such patent laws specially for stem cell patents so as to design such policies which not only allow economic growth but also have adequate accommodation of moral and ethical concern.¹²

The patent filing using stem cells in regenerative medicines is very active.. Upon a preliminary search, it is found that, the applications in this field are mainly filed by the USA, European, Japan and Korean applicants. The top 5 countries that have most registered patent in hESCs were: U.K. (7053 patents), U.S.A (3806 patents), Japan (538), China (463), and Korea (425).¹³ This Paper will be discussing more detailed aspect of Patent filling process in field of Human embryonic stem cell research in India.

RESEARCH METHODOLOGY:

The researcher in this paper has used the Doctrinal method of research.

The researcher has included Legislations, Regulations, Guidelines and Rules made by the competent legislative authority in India that are relevant to the researcher's topic, as the Primary source of research.

The researcher has also included some of the relevant judgments passed by the Competent Authorities. The researcher also included the scholarly articles and journals as the secondary resource.

⁹ Gupta, R. (2018, December). Morality And Ethics Embracing Biotechnology Patents. 41–47. Retrieved from http://proceeding.conferenceworld.in/Pune_RISE-18-Conference/TJP5Q3leP729.pdf (Last Accessed January 14, 2021)

¹⁰ Mukhopadhyay, C., & Mathur, J. (2011). Prospects and Ethical Concerns of Embryonic Stem Cells Research-A Review. *Veterinary World*, 281. Retrieved from https://www.researchgate.net/profile/Dr_C_S_Mukhopadhyay/publication/235956178_Prospects_and_Ethical_Concerns_of_Embryonic_Stem_Cells_Research--A_Review/links/00463514c8c5ae2706000000/Prospects-and-Ethical-Concerns-of-Embryonic-Stem-Cells-Research--A-Review.pdf (Last Accessed July 8, 2020)

¹¹ Office of the Controller General of Patents, Designs and Trademarks. (2013, March). *Guidelines For Examination Of Biotechnology Applications For Patent*. Intellectual Property India. https://ipindia.gov.in/writereaddata/Portal/IPOGuidelinesManuals/1_38_1_4-biotech-guidelines.pdf (Last Accessed Feb.16, 2021)

¹² Singh, R., & Singh, K. (2018). Biological patent and patentability. *Integrated Journal of Social Sciences*, 5(2), 35–40. Retrieved from <http://www.pubs.iscience.in/journal/index.php/ijss/article/view/859> (Last Accessed January 13, 2021)

¹³ Rao US, Arakeri G, Kar A, Sharma B. Patenting pathways: A practical primer. *J Head Neck Physicians Surg* 2020;8:67-9. Retrieved from https://www.researchgate.net/profile/Ankita_Kar3/publication/347486356_Patenting_Pathways_A_Practical_Primer/links/5fddbf492851c13fe9c7200/Patenting-Pathways-A-Practical-Primer.pdf (Last Accessed January 25, 2021)

CONCEPT OF STEM CELLS RESEARCH

Abbaspanah in his article specifies that, at least billion cells die every day in an adult human body. In the same article the author further analysis about stems cells and also suggests that stem cells which are extracted from human embryos are called hESC, the one extracted from adults are ASC and from umbilical cord are known as cord blood stem cells respectively.¹⁴¹⁵

Tripathi, in his article, provides the types of stem cells which are divided into three categories namely Totipotent: Zygote, Pluripotent: Blastocyst, iPSC and Unipotent/Multipotent : Bone Marrow etc Further the author also quotes that, when stem cells divide, they either form different new cells or remain as stem cells.¹⁶

Dakhore in his article suggest that hESC should be considered as father of all cells for all the features it has to develop all the types of cells in human body. The author further explain the place from which they can be extracted and the utilization of same. In the same article the author has also given the utilization of hESC. The author also mention in brief the discovery of Induced Pluripotent Stem cells (hereinafter mentioned as iPSC), and discussed the comparison between hESC and iPSC and how unlike hESC, iPSC do not have any ethical issues.¹⁷

As discussed by Bhalke, iPSC are formed from adult stem cells which are genetically reprogrammed to become different cell types which can further be reprogrammed to become ESC. Author has also mentioned the success story of discovery of first iPSC which was reported by Yamanaka in 2006 on mammal (mouse). Further in same article different years of discovery with regards to iPSC are discussed which include 2009's patent application was made with regard to same which was granted in 2011.¹⁸

De Peppo through an article has discussed that, how we can now generate various quantities of hESCs and iPSCs. In the article the author also describes, how hESCs and iPSCs are different from Adult stem cells (hereafter mentioned as ASC). According to the author's research ASCs are multipotent i.e. they can form only such cells in which they are part of e.g. bone marrow cells forming bone marrow, cardiac tissues forming cardiac tissue and so on. Thus, adult stem cells are organ specific stem cells. Thus according to author, ASCs to have a limited scope are largely used for experimental and clinical tissue engineering. The author further clarifies that, as ASCs are multipotent they do not function properly and many a times are declined by the

¹⁴ Abbaspanah, B., Abroun, S., Zarrabi, M., Mozdgir, A., & Mollanouri, M. (2020). Stem Cell Therapy: A Promising Approach in Treatment of COVID 19. Current stem cell research & therapy, Retrieved from <https://doi.org/10.2174/1574888X15666201012165700> (Last Accessed January 23,2021)

¹⁵ Ahmad Alaie, S. (2015). Stem Cell Treatment as Innovation in Sustaining Socio-Economic Condition in Health Care Sector in India. *Journal of Stem Cell Research & Therapy*, 05(03), 1–7. Retrieved from <https://www.longdom.org/open-access/stem-cell-treatment-as-innovation-in-sustaining-socioeconomic-condition-in-health-care-sector-in-india-2157-7633-1000269.pdf> (Last Accessed July 5, 2020)

¹⁶ Tripathi, M., & Singh, S. (2015). Stem cell technologies in human health: Boon or bane? *Journal of Biosciences and Medicines*, 03(11), 16–24. Retrieved from <https://www.scirp.org/journal/paperinformation.aspx?paperid=60892> (Last Accessed October 8, 2020)

¹⁷ Dakhore, S., Nayer, B., & Hasegawa, K. (2018). Human Pluripotent Stem Cell Culture: Current Status, Challenges, and Advancement. *Stem Cells International*, 2018, 1–17. Retrieved from <https://pubmed.ncbi.nlm.nih.gov/30595701/> (Last Accessed January 13,2021)

¹⁸ Devarapalli, P., Bhalke, S. L., Dharmadhikari, N. S., Mishra, V., Mago, N., Deshpande, N., & Hirwani, R. (2017). Induced Pluripotent Stem Cells: Inventors turning into competitors. *Journal of Commercial Biotechnology*, 22(4), 19–25. Retrieved from https://www.researchgate.net/publication/312469196_Induced_Pluripotent_Stem_Cells_Inventors_turning_into_competitors (Last Accessed January 13,2021)

recipient causing lot of after-effects on patient unlike the pluripotent cells which have always been considered better for their performance and better acceptance from the body.¹⁹

hESC vs. iPSC

According to Tripathi, both hESC and iPSC offer excellent ground for technological advancement. The hESCs are Pluripotent cell found in embryos extraction of which caused lot of ethical issues in various countries. The discovery of iPSCs surely resurrected the dying stem cell research as now there were these cells which are Pluripotent and can be chemically changed to embryonic nature but won't have any ethical issue.²⁰

As explained by Khan, the iPSC have shown many negative impacts on the patient. The author in the article have point out similarity a well differences between hESC and iPSC. According to author hESC and iPSC do have similar features of pluripotency but still iPSC have always been a secondary choice for the scientist to be utilized on humans. The hESC have a lot of potential to cure some incurable diseases and if allowed to research it can lead to enormous change in medical science by curing some incurable disease²¹

According to Marolt, scientist have a keen interest in researching on hESC and iPSC for the features they have and the scientist can also study various functioning of human body and human diseases through studying the functioning of hESCs. The scientist are sure to create regenerative medicine is for different diseases if allowed to study hESC is in detail.²²

As per view given by Singh, the research done on stem cell cannot be concluded by getting few case studies but requires case observation of various case studies to come to a proper and more accurate conclusion. This process takes lot of time money and physical and mental strength. We cannot ignore the positive aspects of stem cell technology but we should not forget that it is a very new and need investigation before introducing any regenerative medicine made for public consumption.²³ Whereas in Lohmor's view, ethical issues have always proven burden on the research using hESC but same was solved after introduction of iPSC which has now enabled a researcher to give stem cell treatment from library to patient.²⁴

ETHICAL CONCERNS RELATION TO STEM CELLS:

Ethical issues can be understood from the utilitarian and deontological ethical philosophies. According to Utilitarian philosophy, the consequences of stem cell utilization should be judged by looking into the ratio of acceptance and rejection of its utility. That means the scholars of utilitarianism believed that Embryo is only a spare part of the body and can replace lost or damaged cells in the body. They seem an ethically acceptable trade-off to destroy embryos for the prospect of saving human lives or curing diseases.

¹⁹ De Peppo, G. M., & Marolt, D. (2012). State of the Art in Stem Cell Research: Human Embryonic Stem Cells, Induced Pluripotent Stem Cells, and Transdifferentiation. *Journal of Blood Transfusion*, 2012, 1–10. Retrieved from <https://www.hindawi.com/journals/jbt/2012/317632/> (Last Accessed October 13, 2020)

²⁰ Tripathi, M., & Singh, S. (2015). Stem cell technologies in human health: Boon or bane? *Journal of Biosciences and Medicines*, 03(11), 16–24. Retrieved from <https://www.scirp.org/journal/paperinformation.aspx?paperid=60892> (Last Accessed October 8, 2020)

²¹ Khan, F. A., Almohazey, D., Alomari, M., & Almoftay, S. A. (2018). Isolation, Culture, and Functional Characterization of Human Embryonic Stem Cells: Current Trends and Challenges. *Stem Cells International*, 2018, 1–8. Retrieved from <https://pubmed.ncbi.nlm.nih.gov/30254679/> (Last Accessed January 10, 2021)

²² De Peppo, G. M., & Marolt, D. (2012). State of the Art in Stem Cell Research: Human Embryonic Stem Cells, Induced Pluripotent Stem Cells, and Transdifferentiation. *Journal of Blood Transfusion*, 2012, 1–10. Retrieved from <https://www.hindawi.com/journals/jbt/2012/317632/> (Last Accessed October 13, 2020)

²³ Tripathi, M., & Singh, S. (2015). Stem cell technologies in human health: Boon or bane? *Journal of Biosciences and Medicines*, 03(11), 16–24. Retrieved from <https://www.scirp.org/journal/paperinformation.aspx?paperid=60892> (Last Accessed October 8, 2020)

²⁴ Lohmor, S. (2020, May 1). Current status of Regulatory perspectives on Stem Cell Therapy in India. *Chemical Biology Letters*, 7(3). Retrieved from <http://pubs.icscience.in/journal/index.php/cbl/article/view/1042> (Last Accessed January 27, 2021)

On the other hand, deontological philosophers believe if stem cells is used for a right research that one should not be worried about its consequences. The deontological thinkers give a picture to think about using Embryonic Cell, that is, whether the use of the Embryonic Cell is right in itself, which destroys an Embryo in its action. This idea of deontology raises ethical opposition against the use of Stem Cells.

Khan in his article try to explain the ethical, social and legal issues related to hESC. The author explains that though science have goes beyond imagination and now new technologies which have used hESC have gain popularity but still ethical, social and legal issues have certainly impacted the researchers. According to author, if such obstacles are removed from these kinds of research they will surely help in tremendous growth in regenerative medicine.²⁵

Further, Shannon in an article has explained how an aborted fetal tissue was used to develop chicken pox vaccine that ultimately had a widespread health benefit. The author used this example to prove that though sometimes usage of hESC may have some ethical, social and legal issues but they can be used to make different regenerative medicines not only helping the people at large to be benefitted by same but also be a multi-billion dollar industry in near future.²⁶

STEM CELL AND BUSINESS

As per research of Asghar²⁷, stem cells ability to be used for regenerative medicines, drug screening and tissue engineering are some of the important properties of stem cell. People suffering from diseases like Splenomegaly²⁸, Autism²⁹, the diseases related to nervous system³⁰, insulin/diabetes³¹, high blood pressure³², dementia etc certainly have greater faith on the stem cells and its capability to treat these incurable diseases.

According to Devarapalli, lot of medical conditions happens due to loss or malfunctioning of some tissues or some organs. The author further states that, such Situation can cause distress disability and even death unless the person receives implantation from any other person or some other devices. Eventually in this Article the author explains how the stem cell replacement therapy has gained popularity in whole world and usage of hESC in same has given it more hopes of success because of the ability of hESC to form any cell type.³³

²⁵ Khan, L. (2008). Ethics Analysis of the Human Embryonic Stem Cell Research Debate. *Online Journal of Health Ethics*, 5(2). Retrieved from <http://dx.doi.org/10.18785/ojhe.0502.04> (Last Accessed January 20,2021)

²⁶ Shannon, T. A. (2001). Human Embryonic Stem Cell Therapy. *Theological Studies*, 62(4), 811–824. Retrieved from <https://journals.sagepub.com/doi/abs/10.1177/004056390106200407> (Last Accessed July 24, 2020)

²⁷ Asghar, W., El Assal, R., Shafiee, H., Anchan, R. M., & Demirci, U. (2014). Preserving human cells for regenerative, reproductive, and transfusion medicine. *Biotechnology Journal*, 9(7), 895–903. Retrieved from <https://onlinelibrary.wiley.com/doi/abs/10.1002/biot.201300074> (Last Accessed October 19, 2020)

²⁸ Dewanjee, M. (2016). Stem Cell Therapy Its Challenges, Successes, Failures And Potential Applications : On-Going Translational Research. *Science And Culture*, 2016, 278–294. Retrieved from <http://www.scienceandculture-isna.org/sept-oct-2016/03%20Mrinal%20K%20Dewanjee.pdf> (Last Accessed January 12,2021)

²⁹ Siniscalco, D., Kannan, S., Semprún-Hernández, N., Eshraghi, A. A., Brigida, A. L., & Antonucci, N. (2018). Stem cell therapy in autism: recent insights. *Stem Cells and Cloning: Advances and Applications*, Volume 11, 55–67. Retrieved from <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6204871/> (Last Accessed January 12,2021)

³⁰ Gao, J.-Y., Zhang, W., Hu, S.-Q., Zhang, L., Chen, T.-Y., Tang, B., Zhang, Z.-, & Hu, J.-B. (2020). In vitro and in vivo induction of human embryonic stem cells differentiated into rosette neural stem cells and further generation of neuron-like cells. *All Life*, 13(1), 466–473. Retrieved from <https://www.tandfonline.com/doi/citedby/10.1080/26895293.2020.1808082?scroll=top&needAccess=true> (Last Accessed January 13,2021)

³¹ Kleiderman, E., Boily, A., Hasilo, C., & Knoppers, B. M. (2018). Overcoming barriers to facilitate the regulation of multi-centre regenerative medicine clinical trials. *Stem Cell Research & Therapy*, 9(1), 1–8. Retrieved from <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6225696/> (Last Accessed January 23,2021)

³² | A. (2019, May 22). Placental stem cells can regenerate new heart cells after heart attack, study finds. *ANI News*. Retrieved from <https://www.aninews.in/news/health/placental-stem-cells-can-regenerate-new-heart-cells-after-heart-attack-study-finds20190522160353/> (Last Accessed July 10, 2020)

³³ Devarapalli, P., Bhalke, S. L., Dharmadhikari, N. S., Mishra, V., Mago, N., Deshpande, N., & Hirwani, R. (2017). Induced Pluripotent Stem Cells: Inventors turning into competitors. *Journal of Commercial Biotechnology*, 22(4), 19–25. Retrieved from https://www.researchgate.net/publication/312469196_Induced_Pluripotent_Stem_Cells_Inventors_turning_into_competitors (Last Accessed January 13,2021)

PATENTABILITY OF STEM CELL

In year 2000, Indian Doctors and hospitals made some controversial claims regarding treatment through stem cells. Some of these false and commercial treatment gave emergence to guidelines for stem cell research. Lifeline Hospital Chennai, for instance, claimed that injection of stem cells could help "improve nerve function" following spinal cord injury. However, this lacks clinical evidence. Tiwari states that India plays an important role in stem cell research and various researchers are supported by government to do research in hESC which are derived from IVF or donated embryos.³⁴

In 2007, Indian Council of Medical Research (ICMR) had, for the first time, issued a guideline with an objective to ensure that research will be carried keeping in mind ethical issues and there will be a good quality of stem cell research. There were many shortcomings which were pointed out by many scholars from time to time. As a result, in 2017, new guidelines as National Guidelines for Stem Cell Research (NGSCR) 2017 were introduced by the Indian Council of Medical Research and the Department of Biotechnology.

ESSENTIAL FEATURES OF THE NGSCR GUIDELINES 2017

1. Stem cell research was divided in three broad categories as:³⁵
 - a) Permissible Stem Cell Research: Here the guidelines have allowed development of new hESC/ (iPSC) lines
 - b) Restrictive Stem Cell Research: According to the guidelines the research which involves pre implantation embryo of human processed for IVF or IUI treatment needs prior permission of done and the committee
 - c) Prohibited Stem Cell Research: Reproductive cloning studies, human embryos beyond 14 days³⁶ of fertilization and human germ line gene therapy falls under prohibited research category.
2. They have now introduced 3 levels of manipulations which are created for stem cell research viz. minimal, substantial, and major.
3. With prior approval of IC-SCR and IEC, derivation of new hESCs or iPSC lines from human embryonic or somatic cells, respectively, have to follow the conditions given in the guidelines.
4. The guidelines is not applicable to the research where nonhuman stem cells and their derivatives are used nor to hematopoietic stem cells and also are not applicable to PRP and autologous chondrocyte/osteocytes implantation which are categorized as "other cell-based applications"

CURRENT LEGISLATURE FOR PATENTING IN THE UK, USA, AND INDIA

1. The United Kingdom³⁷

The debate on moral, ethical, and religious values ends up in the United Kingdom with the Human Fertilization and Embryology Act 1999. The Act allows the usage of an embryo for research only less than 14 days of fertilization. The research work can be carried out only after taking a license for the same purposes from the authority established under the Act. Cloning

³⁴ Tiwari, S. S., & Raman, S. (2014). Governing stem cell therapy in India: regulatory vacuum or jurisdictional ambiguity? *New Genetics and Society*, 33(4), 413–433. Retrieved from <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4226321/> (Last Accessed July 15, 2020)

³⁵ Moradi, S., Mahdizadeh, H., Šarić, T., Kim, J., Harati, J., Shahsavaran, H., Greber, B., & Moore, J. B. (2019). Research and therapy with induced pluripotent stem cells (iPSCs): social, legal, and ethical considerations. *Stem Cell Research & Therapy*, 10(1). <https://doi.org/10.1186/s13287-019-1455-y>

³⁶ Though the limit of 14 days is now removed by International Society of Stem Cell research in 2021 but no change is done as such in our national guidelines

³⁷ O'Shea, O., & Abranches, E. (2020). UK Stem Cell Bank. *Stem Cell Research*, 49, 1–4. Retrieved from <https://www.sciencedirect.com/science/article/pii/S1873506120303202> (Last Accessed February 17, 2021)

the embryos for research was also made legal by the Act. The Human Fertilization and Embryology Authority is a statutory supervisory body established to issue licenses to laboratories taking up research work on embryos and checking proper compliance with the rules and regulations under the Act. However, the Act itself underlines certain conditions before applying for the license. For example, embryos must not be used beyond 14 days for research purpose. They must be shown that it is necessary or desirable to use embryos to achieve the research aims. In 2001, Act was amended with regulation allowing embryo research for specific other purposes, including understating the development of an embryo and treating severe diseases. The UK has also passed the Human Reproductive Cloning Act 2002, which bans the cloning of embryos for reproductive purposes. In 2008 a new authority called the Regulatory Authority for Tissue and Embryos (RATE) was set up under the Human Tissue Act 2004 to govern hESC research.

Patentability of Stem Cell:³⁸ Having a very conservative scope of stem cell and moral requirement for patentability in the United Kingdom, the directive issued by the patent office reveals that human embryos if are used for industrial or commercial purposes than they not patentable. The UK Patent Office further given the difference between totipotent and pluripotent cells and stated that while former are non-patentable but later can be patented.

2. The United States of America³⁹

In the USA there is no federal law which regulates Stem cell research. Thus, Stem cell research was never been banned but there were certain restriction on funding for same which were changed from time to time. For reference, former President of the U.S.A, George W. Bush by passing an ordinance in 2001 permitted the funding for hESC research only if such cells lines were obtained from previous stem cell lines. Then later in 2009 President Barrack Obama extended the scope further by another executive order which permitted the use of hESC even if they are not obtained from the previously generated stem cell lines. However, in the absence of any federal legislation, individual states are free to make their own legislation.

Patentability of Stem Cell:⁴⁰ In the US, despite conflict for funding to stem cell research, US Patent Law allows that stem cells and methods of making or using stem cells can be patentable. It is because US patent law has no requirement of morality for patentability.

3. India

Sunil Mani in an article has explained the journey of patent laws since 1883 till 2020. According to the author, until 19th century, patent law where only national affairs. In 1883, 11 countries signed Paris convention which was considered as first of its kind of multi lateral treaty. Then WIPO (World Intellectual Property Organization) came in picture in 1967 which was supported by various countries but soon conflicts started taking place which caused lot of problems. GATT (General Agreement on Tariffs & Trade) was signed in 1986 to claim such conflicts but that too lasted only for some years. Finally TRIPS (Trade related aspect of Intellectual property rights) came in force and WTO (World Trade organization) replaced GATT on 1st January, 1995. Author explains the importance of Article 27 of TRIPS which discuss the patentability clause which basically has 3 aspects which are Novelty, Inventive steps and it should be capable of Industrial

³⁸ Odell-West, A. (2020). *Invention and the Human Embryo*. *Intellectual Property Quarterly*, (1), 1-19. [1]. Retrieved from https://www.research.manchester.ac.uk/portal/files/131903414/Invention_and_the_Human_Embryo.pdf (Last Accessed September 24, 2020)

³⁹ Jose, J., George, T., & Thomas, A. M. (2020). *Regulation of Stem Cell-Based Research in India in Comparison with the US, EU and other Asian Countries: Current Issues and Future Perspectives*. *Current Stem Cell Research & Therapy*, 15(6), 492–508. Retrieved from <https://www.ingentaconnect.com/contentone/ben/cscr/2020/00000015/00000006/art00003> (Last Accessed January 27, 2021)

⁴⁰ Ibid at 36 page 15

Application which is the similar grounds for granting the patents in all countries in the world. Article 27 also talks that countries may deny patentability on basis of against morality or public policy.⁴¹ According to Singh, Indian Patent act also emphasize Article 27 as essentials for grant of patent.⁴²

The Indian Patent Act, 1970 under section 3(b) provides that any invention contrary to morality or public order and will seriously prejudice human, animal or plant health will not be patentable. Considering the ethical and moral grounds, it can be argued that stem cells cannot be patented in India. For instance, though the draft of 2008 stated that hESC patents are against public order and morality, 2011 draft does not specifically mention hESC are non-patentability. In the absence of specific guidelines, hESC can be considered as a patentable subject matter but of course subject to Section 3 of the Indian Patent Act, 1970.

Parvatam tried to explain the essentials of Patent laws in India by explaining the terms:

- 1) Novelty - invention not available to people before
- 2) Non-obviousness - shouldn't be in trivial variation of something already known
- 3) Utility - invention to have some known use

Thus the author also discussed Budapest Treaty on the International Recognition of the Deposit of Microorganisms and its adoption by India in 2002 which author suggest that it has enlarged the scope of making biomedical patent access easier for the researchers.⁴³

According to Devaiah, if at early stage of biomedical research a researcher finds that the contents in his research are against morality then he won't move forward with the research as he won't be getting patent for the same. Whenever patents are filed for any biological material the source of getting such material shouldn't be against public morality or else it can get rejected. Patentees want a patent to achieve monopoly in the market. Indian patent law gives no room for patents for such biological research in which material is taken from such source which is considered unethical and against public morality. "Come to the law with clean hands" is principle which is followed in everywhere in India including all the patent offices.. There is a lack of developed jurisprudential principle in Indian patent law which often put researchers under uncertainty and confusion. Patent office or no more just concerned about granting the patents but they also play a key role when it comes to not granting patents for such research which falls under the ambit of against public morality.⁴⁴

According to Sheeraz the basic problems in research in biomedical sector which includes stem cells research in India as per the five years plan (2007-2012) are:⁴⁵,

- 1) No policy on national health research
- 2) Health research system though present is very weak
- 3) Inadequate governance to plan and implement the laws with regards to stem cell research


⁴¹ Sunil Mani (2020): India's patenting record since TRIPS compliance of her patent regime, Asian Journal of Technology Innovation, Retrieved from <https://doi.org/10.1080/19761597.2020.1829977> (Last Accessed January 25, 2021)

⁴² Singh, R., & Singh, K. (2018). Biological patent and patentability. Integrated Journal of Social Sciences, 5(2), 35-40. Retrieved from <http://www.pubs.iscience.in/journal/index.php/ijss/article/view/859> (Last Accessed January 13, 2021)

⁴³ Parvatam, S., Bharadwaj, S., Radha, V., & Rao, M. (2020). The need to develop a framework for human-relevant research in India: Towards better disease models and drug discovery. Journal of Biosciences, 45(1), 1-14. Retrieved from <https://link.springer.com/article/10.1007/s12038-020-00112-8#citeas> (Last Accessed January 27, 2021)

⁴⁴ Devaiah, V. H. (2010). Impact of bioethics on patentability of inventions. Indian Journal of Medical Ethics, 7(1), 14-18. Retrieved from <https://pubmed.ncbi.nlm.nih.gov/20166289/> (Last Accessed October 20, 2020)

⁴⁵ Ahmad Alaie, S. (2015). Stem Cell Treatment as Innovation in Sustaining Socio-Economic Condition in Health Care Sector in India. *Journal of Stem Cell Research & Therapy*, 05(03), 1-7. Retrieved from <https://www.longdom.org/open-access/stem-cell-treatment-as-innovation-in-sustaining-socioeconomic-condition-in-health-care-sector-in-india-2157-7633-1000269.pdf> (Last Accessed July 5, 2020)

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- 4) No proper monitoring or evaluation system provided
 - 5) No adequate funding for research related to stem cells
 - 6) No strong inter agency collaborations with governmental or private sectors
 - 7) Limited access of health research information and its utility

According to Tallmadge, in last few decades the international community is engaged in drawing a margin between patentable and non-patentable subject matters. Through this many nations are developing their own patent policy suitable as their wants and traditions.⁴⁶

CONCLUSION:

After discussing the meaning, objective, and importance of stem cell research, the therapeutic use of stem cell research in the future cannot be denied. Even we have seen that Mesenchymal stem cells can be a promising treatment for COVID-19. We have seen that no significant concern has been raised against the Adult Stem Cell, but there has been much controversy regarding using Embryo Stem Cells. The UK has comprehensively dealt with it and enacted the HFA Act as far as the legislative framework. Nevertheless, there are certain loopholes, like the phrase 'necessary and desirable' for issuing a license is uncertain. The phrase 'serious disease' is not clearly defined.

On the other hand, the US has never developed any federal law on stem cell research. The legislative condition in India more effective than US and less than the UK as India have enacted the National Guidelines on Stem Cell Research, 2017. Though these guidelines are comprehensive but Indian researchers still face lot on uncertainties with regards to stem cell research. For reference, in Mr. Raghubir Singh and another vs. Union of India and Another⁴⁷, the court by passing a judgment has asked the clinic to continue embryonic stem cell therapy for their patients even if there is no approval as per the New Drugs and Clinical Rules, 2019. Even though, the need of proper Legislature is still need of an hour so that we can achieve great heights in stem cell research.

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⁴⁶ H. Tallmadge, E. (2019). Nationalizing Trips: An Examination Through Exceptions. *The John Marshall Review of Intellectual Property Law*, 18, 285–324. Retrieved from <https://repository.law.uic.edu/cgi/viewcontent.cgi?article=1457&context=ripl> (Last Accessed January 12, 2021)

⁴⁷ Shikha Through Her Legal Guardian / Next Friend Mr. Raghubir Singh V. Union Of India And Anr, W.P.(C) 6057/2019(2019)(India)

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