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Stem Cell Patenting: Moral and Legal Dilemma

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Humans in the era of 21st century have witnessed development at its epitome, coupled with obvious pros and cons. Their greed has led to over exploitation of resources, causing irreversible damages. Presently, the positive aspects of development seem to overshadow the negatives. Increased life span, mortality rate, better health facilities and treatment of incurable diseases are some affirmative outcomes of development. One such recent phenomenon is stem cell therapy. The credit for the discovery being spotlighted goes to scientists John Gurdon and Shinya Yamanaka, who were awarded the Nobel Prize in 2012 for discovering that ordinary cells of a living organism can be reprogrammed or changed into stem cells, which can further turn into any other tissue of the body. Owing to this breakthrough, the treatment of incurable diseases like cancer does not seem to be a distant dream. However, it is shadowed by concerns from critics on the grounds of morality due to its nature of procuring living components to get patents. In this paper, the author discusses the concept of stem cell therapy, the present legal scenario *vis-à-vis* its patentability and the ongoing debate regarding legal and moral implications of stem cell patenting.

Keywords: Adult Stem Cells, Embryonic Stem Cells, Stem Cell Therapy, Patent, Life Form, Biotechnology Directive, Public Ordre and Morality, European Patent Convention

One commonality that exists between every living creature existing on Earth is cells.[1] A cell is a basic unit of life or the lowest common denominator of life. An organism may be single cellular with only one kind of cell for instance the protozoa microbe or multicellular like humans, with different kinds of cells. In fact, the human body consists of as diverse as 200 kinds of cells.[2] These cells perform various functions in the body and collectively form tissues. The tissues collectively organize into organs which in turn form an organ system in the body. Each organ system in the human body has a specific function it performs. A stem cell is one of the cells present in the living organism which possess no less than magical qualities of transforming themselves into other kinds of cells in the body.[3]

These self-replenishment characters of the cells allow them to serve as a repair system for the body. Two unique characteristics that differentiate it from other cells in the body are:

(i) These cells do not have a designated or specified function. They only bear the potential of self-renewal through the process of cell division. For instance, in organs like the bone marrow stem cells divide frequently to replenish the worn-out cells.

(ii) These cells also bear the potential of transitioning into a tissue or an organ specific cell, which has a specific function to perform in the body.[4]

Understanding the potential of stem cells entails the primary understanding of the concept of stem cell therapy, the source and the underlying controversy, which bears much similarity to the objections witnessed by gene patents.

Sources of Stem Cells

Science holds unmeasurable potential to serve as a boon and provide treatments for a number of fatal diseases. While an aspect of sciencereflects pure technology, it is often coupled with living beings or parts of living beings to transform into a product which has drastic impact in the favour of human civilization Stem cell therapy is one such sphere which has witnessed and reflected immense potential towards the treatment of a number of life threatening diseases and deformities in humans. For its application, the technology is fused with the stem cells procured from various sources of the human body, depending upon the illness or disease which is

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being aimed to be treated. These sources can broadly be classified into two categories: adult body tissues, which are present in the form of multipotent or unipotent stem cells, and human embryos, existing in the form of pluripotent stem cells.

Adult Stem Cells

Stem cells exist throughout their lifetime in the human body and can be utilized at any point of time. These show existence in the body from the moment an embryo comes into existence i.e. the postnatal stage.[5] They remain present in an undefined state until required by the body for a specific purpose. The natural wear and tear of cells on a day to day basis may require the stem cells to repair and grow new tissues in place of the old ones. An adult stem cell carries the characteristic of 'self-renewal' through the process of cell division. This implies the potential of the cells to give rise to different kinds of cells.[6] The importance of these cells was brought to light in 1999 when researchers[7] established the multipotency of these cells. The adult stem cells derived from bone marrow or 'Mesenchymal stem cells' are located in all the tissues in the body[8] and are important as they are responsible for repairing of cells through renovation.

Embryonic Stem Cells

These stem cells, as the name itself suggests, are derived from embryos. Research on stem cells derived from embryos, scientifically referred to as embryonic stem cells, began in 1998, when scientists started harvesting them from early stage of embryo development. The embryo at this stage of harvesting is known as blastocyst, which occurs approximately five days after fertilization. These cells today are at the vanguard of drug discoveries and are a huge source for cell-based therapy for treating injuries and diseases.

Embryonic stem cells are pluripotent in nature i.e. they bear the capacity to contribute to all kinds of tissues existing in the body.[9] These stem cells are generally derived from embryos developing from fertilized eggs in early stage of pregnancy. The fertilization of the egg takes place when the sperm and the egg combine to form a single cell called the zygote.[10] The zygote begins to divide itself and an embryo is formed. This embryo turns into blastocyst after almost 3-5 days of fertilization. The 4-5 days old blastocyst is the source of embryonic stem cells which get implanted in the womb. The peculiarity of these eggs is that they are fertilized in vitro[11] and then donated for experimentation purpose with the consent of respective donors. The pluripotency of the cells grants them the unique characteristics of unlimited life span and expanding potential. The blastocyst consists of two kinds of cells-

(i) Inner cell mass or the ICM- which develops into fetal tissues,

(ii) The outer mass cell or Trophectoderm- which develop into the extraembryonic tissues such as the placenta.[12]

It is the inner mass cell that is the source of embryonic stem cells.[13] In the early phase of pregnancy, the blastocyst stage lasts about 5 days. After this period the embryo gets implanted to the uterus. This is an important stage where the differentiating of stem cells commences.[14] The very first step for growing a stem cell involves extraction of samples from an embryo followed by placing of these extracted cells under a controlled environment to enable division of cells. When the cells are allowed to form clumps they form embryoid bodies and begin differentiating. Differentiating is the process through which a cell undergoes transformation in terms of its gene expression and turns into a more specific kind of cell.[15] The different kinds of cells in the human body as per their ability to differentiate are as follows-

(i) Tutipotent cells- these cells have the ability to differentiate themselves into embryonic and extra embryonic cell types. These cells are produced from the fusion of the male and female gamete which gives rise to zygote.[16] The zygote multiplies to form cells resulting in formation of a viable organism.

(ii) Pluripotent stem cell- pluripotent cells are the progenies of totipotent cells. These cells are considered master cells as they bear the potential to renew nearly any worn out cell in the body. They can thus self-renew and differentiate into almost all cell types existing in an adult organism.[17] Embryonic stem cells fall under this category of cells.

(iii) Multipotent stem cells- these cells also differentiate into other types of cells but are restricted to a specific tissue, where they develop into multiple specialized cells.[18] For instance, the bone marrow is a source of multipotent stem cells which gives rise to all the kinds of cells found in blood only.

(iv) Unipotent stem cells- these can develop into a specific cell type only, which is their own.[19] They have the self-renewal property.

Most of the controversies which revolve around embryonic stem cells emerge from the issue of destruction of the embryo for the purpose of extracting stem cells. Even though the embryo is merely five days old, it is still deemed to be a living creature thereby causing the critics to object to destruction of a living being, irrespective of the purpose or the lives it promises to save. Over a decade ago scientists miraculously created stem cells using dead embryos thereby avoiding the need to deliberately destroy the same. Scientists in Serbia have shown that it is now possible to extract stem cells from embryos which have stopped diving themselves. There are certain embryos which during the process of IVF are not implanted due to visible defects and the same could be used to make stem cell lines.[20]

Future of Stem Cells

The discovery of the potential of stem cell to develop into a variety of cells in 1960 led to researchers relying immense value in the same. A decade later stem cells were identified in mice which led to further research and discovery and the creation of the very first human embryonic stem cells.[21] The dual capacity of stem cells i.e. of self-renewal and differentiation into other types of cells makes them worthy of bearing disease curing capacity and a number of other potential medical advantages. Scientists are aware of the fact that even the most fatal diseases such as cancer occurs due to abnormality in cell division and differentiation.[22] From Parkinson's to Alzheimer, the stem cells have a lot in store thereby creating the perfect atmosphere for the patent regime. A holistic understanding of the therapeutic and curative properties of stem cells and molecular controls of the process involved can prove to be helpful in evolving strategies and cures for many diseases.

Parkinson's for instance is a progressive disease which causes destruction of dopaminergic neurons in the midbrain. This disease affects movement, causes tremors, speech impairment, stiffness etc. Embryonic stem cells carry the ability to differentiate into neural stem cells and subsequently dopaminergic neurons.[23] Induced pluripotent cells[24] and mature multipotent stem cells[25] can also be beneficial for the treatment of Parkinsons,[26] the research on which was previously extremely difficult due to the loss of diseased tissue. One of the most severe neurological damages i.e. to the spinal cord can lead to loss of neuron tissue. The consequence of this harm is loss of sensory and motor functions in the body. The only probable treatment of such damage is through replacement of progenitor cells. A progenitor cell has restricted development potential since it can only take the form of a specific cell in the body.[27]

Another neurodegenerative disease Alzheimer which is a common form of dementia in older humans has seen promising results of cure using stem cells.[28] Dementia is a condition which leads to disturbance of functioning of brain. The cognitive faculties of the brain are impaired leading to difficulty in comprehension, thinking, orientation, calculation etc.[29] Neural stem cells which have the capacity of differentiating into neurons, can be utilized for curing this disease.[30]

Diabetes is another chronic widely occurring disease which occurs due to malfunction of pancreas. The pancreas does not produce sufficient insulin to regulate sugar level in the blood and thus the body cannot effectively use the same. In fact, in the year 2019 itself, approximately 15 lacs deaths were directly caused due to this disease.[31] Researchers have studied various stem cell therapies for treatment of diabetes. For instance, the embryonic stem cells were reported to produce insulin in mouse. Mesenchymal cells, which are capable of making several kinds of cells belonging to skeletal tissues in the body,[32] have also been studied and have reflected the potential of differentiating into insulin producing cells. One of the major causes of morbidity around the world can be attributed to cardiovascular diseases. The almost negligible ability of the cardiac muscle cells to repair itself along with inefficient medications and surgical procedures do not improve the contraction ability of these muscles.[33] Researchers have suggested that cellular therapy has better potential for treatment of cardiovascular diseases by regenerating the injured myocardium.[34]

Thus the potential of stem cells in the field of medicine is so immensely important that continuous research and studies are being conducted to lead to definite results. In such a scenario protecting inventions becomes all the more important and justifiably lucrative. Even so, this area is unexplored when compared with traditional therapeutic

techniques. It is for this reason that there lies immense scope for investigation and expansion of the stem cell horizon, which may not be restricted to therapeutic uses.

Patent Laws in European Union, United States of America and India

Ever since the judgment in *Diamond* v *Chakrabarty*,[35] by the US Supreme Court,placing life forms under patent eligible subject matters, there has been constant evolution in research and development in this field. Certain jurisdictions have welcomed the possibility of patenting life forms with open arms whereas some have been skeptical regarding the consequences of the same.

European Union Patent Law

European Patent Law is derived from the European Patent Organization and the European Union. The most important legislation governing the laws of biotechnological inventions in Europe is the Biotechnology Directive[36] which has also been adopted into the European Patent Convention[37] and thereby applies to patents granted by European Patent Office. European Union has shown support to stem cell research in the form of financial aid.[38] The research grant was for studying and developing human embryonic stem cells as these are the only cells in the body capable of differentiating into any other kind of cell. Thus, the purpose of the grant was to harness this potential but it raised several ethical concerns due to the source of its derivation. The European Patent Conventions lists certain inventions as non-patentable on moral grounds[39] and ineligible subject matter exclusion.[40] The rationale behind morality as an exclusion for patent is that inventions cannot go against the very fabric of public ordre. On the other hand with regard to inventions in the biotechnology field exploiting the human body, it is believed that 'the human body, at various stages of its formation and development and simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable invention.'[41] However, if 'an element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene[42] may constitute a patentable invention, even if the structure of that element is identical to that of a natural element.'[43] Thus the primary challenge is more or less restricted to inventions utilizing human embryos for deriving stem cells. The provision of the Biotechnology Directive specifically bars the usage of human embryos for any commercial purpose. Article 6 of the directive states-

(i) *Inventions shall be considered unpatentable where their commercial exploitation would be contrary to ordre public or morality; however, exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation.*

(ii) *On the basis of Paragraph 1, the following, in particular, shall be considered unpatentable: (c) Uses of human embryos for industrial or commercial purposes.*

Thus, stem cells derived from live, or even dead, embryos clearly fall outside the ambit of patentability. The landmark decision of the Court of Justice of the European Union in the case of *Oliver Brüstlev Greenpeace*[44] *further clarified the stance with regard to human embryonic stem cells. Herein, Greenpeace, an environmental NGO sought to revoke a patent held by Oliver Brustle. The patented invention was regarding 'neural precursor cells' which arise from embryonic stem cells. Interpretation of Article 6(2)(c) of Directive 98/44/EC was one of the major issues which would determine the fate of human embryonic stem cells. The failure to define what 'human embryos' and 'industrial or commercial purposes' entailed led to a variety of interpretations throughout Europe.*

A third question, in addition to the above stated two, was regarding patentability of inventions which require prior destruction of human embryos. The Court of Justice answered the questions by laying down definite meaning of 'human embryo' and also defining the ambit of 'industrial or commercial purpose'. The definition was altered later to allow scope for stem cells made from 'parthenoteseg'". The literal meaning of the Greek word 'parthegenosis' is a mixture of two words i.e. 'Parthenos' meaning virgin and 'genesis' meaning origin.[45] *Thus, the process entails development of an egg without previous copulation. The resulting egg is known as 'parthenotes egg'*[46] *Thus*, 'an unfertilized human ovum whose division and further development have been stimulated by parthenogenesis does not constitute a 'human embryo', (…) if, in the light of current scientific knowledge, it does not, in itself, have the inherent capacity of developing into a human being, this being a matter for the national court to

determine.'[47] *The only exception for usage of the said embryo was therapeutic or diagnostic which was patentable. With regard to the third question the Court stated that inventions will not be patent eligible if "requires the prior destruction of human embryos or their use as base material, whatever the stage at which that takes place and even if the description of the technical teaching claimed does not refer to the use of human embryos*". Thus the legal stand on the patentability of embryonic stem cells is deeply influenced by the morality behind the same. Destruction of human embryos or even publicly available stem cell lines derived after consent of donors are both excluded as has been established by the European Patent Office in the Wisconsin Alumni Research foundation case.[48]

Even though there has been a clear elimination of inventions which are based upon stem cells obtained by destruction of human embryos, a clever interpretation of the same will allow scope for patent over inventions which do not destroy the human embryos to utilize the same. Thus, the restriction will only be applicable to using publicly available human embryonic stem cells which prima facie are derived through destruction of human embryos. It is for the inventor to prove that the source of stem cells used in their invention did not involve destruction of human embryos.

Clarifications were sought regarding the situation of patent with regard to parthenotes in the case of International Stem Cell Corporation[47] The inability of parthenote egg to develop into a fetus due to absence of male genetic material,[49] may trigger leniency from the patent office with regard to eligibility for patent grant. Even with uniformity in the European Patent law, divergent decisions have arisen.[50] Thus this lacuna should be removed so as to have clarity with regard to what does and does not fall within the ambit of patentability.

United States Law

The eligibility for patent in the US is subject to fulfilment of the criteria- (i) Useful;[51] (ii) New;[52] and (iii) Non-obvious.[53] When compared to its European counterpart, the US Patent Law does not restrict its ambit on moral considerations. Patent on life forms are statutorily permitted but inventions based on humans including human embryos and fetus fall outside the purview of patentability.[54] The United States practices the approach to differentiate between cloned embryos and organs from cells and cell lines which includes human embryonic stem cells.[55]

Even though, the Supreme Court of U.S. observed that "*Congress plainly contemplated that the patent laws would be given wide scope*,"[56] the Court has laid down three exceptions to the subject matter which would not be patent eligible-

(i) Laws of nature
(ii) Natural phenomena, and
(iii) Abstract ideas[57]

To be eligible for patent, the human stem cell must not fall under the abovementioned exceptions specifically under 'natural phenomenon'. Long back USPTO announced that a policy has to be followed with regard to patentability which will not permit human body including embryos and fetus to be subject matter of the same.[58] Even so, the USPTO itself has granted patents over human stem cells.[59] The government's attitude towards stem cell research has been unclear as in 2009 President of the U.S. Barack Obama's executive order allowed funding of research pertaining to embryos,[60] to the legally permissible extent.[61] The provisions of 2011 Leahy-Smith America Invents Act (AIA) that "*no patent may issue on a claim directed to or encompassing a human organism*" is one of the most significant legislations in the field of biotechnology inventions. This act permits patenting of stem cells but restricts inventions from patentability which utilize human organism including embryos.[62] Landmark judgements have been given by the US Supreme Court which has drastically expanded the patenting horizons for stem cell based inventions.

The Myriad Saga

In the case of Association for *Molecular Pathology* v *Myriad Genetics Inc.,*[63] the Supreme Court settled the confusion with regard to gene patenting. Herein, *Myriad Genetics* had successfully patented the precise location of two genes namely BRCA1 & BRCA2. The mutation of these genes could increase the risk of breast and ovarian cancer respectively. Locating the sequences in the body Myriad had developed comprehensive diagnostic tests for these genes. As per the decision given by the Apex Court of the US only cDNA is patent eligible and not isolated & purified genes. cDNA is the DNA which is created synthetically on an RNA template. Such a DNA is devoid of the non-coding region or intron which makes it non-naturally occurring gene and thus

eligible for patent.[64] The Court also stated that "*We merely hold that genes and the information they encode are not patent eligible under §101 simply because they have been isolated from the surrounding genetic material*." Thus, a gene being a 'product of natur'[65] cannot be patented if it is in its naturally occurring form and even merely isolating the non-coding region will not remove this defect. It was on this basis that most of the patents of Myriad were invalidated except the ones based on cDNA.

This decision has undermined the patent eligibility of human embryonic stem cells since isolated & purified hESCs are identical to hESCs in human blastocysts. The decision led to USPTO issuing new set of guidelines for examiners to be applied specifically to inventions pertaining to biotechnological inventions, which were released in 2014[66] and supplemented later by two updates in 2015[67] and 2016.[68] The release of these guidelines enhanced the examining standards resulting in increase of rejections of patent claims of biotech inventions. This poses as a major hurdle to stem cell inventions as essentially these cells are pure product of nature.Except for the process of their production even induced pluripotent stem cells obtained using exogenous genes will not show any 'markedly different' property from the stem cells occurring naturally. As opposed to this, the organs and tissues regenerated from these cells will be patent eligible as they will not be exactly as the naturally occurring organs and tissues. Similarly, new characteristics for instance extended life span or immunity against a specific disease etc., developed using these stem cells by human efforts will be patent worthy too. In a product by process claim the product of the claim is examined and not the production process. Thus, stem cell inventions based on product by process claims will have to abide by the 'markedly different characteristics' standard to be eligible for patent. The claims based on methods may have a better shot at getting patent considering the unclear scenario of stem cell patents. As long as the method shows significant difference from an already existing natural process, the claim would be patent eligible. Thus, the claims have to evidently highlight how the method is 'significantly different' than a natural one.

Indian Patent Law

The potential of stem cells in the medicine world has motivated Indian researchers and development agencies to work in this sector. The Indian Patents Act, 1970 lays down the following conditions as eligibility criteria for patent grant:

(i) Novelty or New product;[69]
(ii) Inventive step;[70] and
(iii) Industrial application[71]

In addition to these criteria, an invention should not fall under the ineligible subject matter as mentioned in the Indian Patents Act.[72] Even if stem cells qualify the first three criteria, they fall under the ineligible subject matter under the provisions of the Act. For instance, Section 3(b) states that "*an invention the primary or intended use or commercial exploitation of which could be contrary public order or morality or which causes serious prejudice to human, animal or plant life or health or to the environment*". The source of stem cells specifically human embryonic stem cells requires destruction of embryos which makes the invention fall under this provision thereby prohibiting its patentability. Further, Section 3(j) states that "*plants and animals in whole or any part thereof other than micro-organisms but including seeds, varieties and species and essentially biological processes for production or propagation of plants and animals*", thereby eliminating any possible scope for stem cell patenting. Section 3(i) states "*any process for the medicinal, surgical, curative, prophylactic [23] [diagnostic, therapeutic] or other treatment of human beings or any process for a similar treatment of animals to render them free of disease or to increase their economic value or that of their products*." By the virtue of this section, India has restricted even process patents inrelation to stem cells.

Even with great established advantages of stem cells, India among other countries has taken its public ordre and morality consideration with utmost seriousness to object to stem cell patents specifically hESCs. The Patents Act does not specifically prohibit patenting of stem cells but critics have resorted to the above-mentioned provisions to ensure compliance with the same.Realizing the undeniable importance of the biotechnological developments and the benefits of stem cells The Office of the Controller general of Patents, Designs & Trademarks has time to time issued guidelines to help the examiners of patents deal with biotechnological invention. This was done after the 2002 Diminaco[73] judgment which opened the doors wide for patentability of living organisms. A set of guidelines were published in the 'Manual of Patent Office Practice and Procedure' as 'Guidelines For Examination of Biotechnology Application' with the objective that "*Guidelines will help the Examiners and the Controllers of the Patent Office in achieving*

consistently uniform standards of patent examination and grant".[74] Another breakthrough achievement was the 2015 "Guidelines for Search and Examination of Patent Applications" which state specific instructions with regard to human embryos. It states-

"*Adequate care should be taken while examining the inventions vis-à-vis their primary or intended use or commercial exploitation and it should be carefully dealt so that the subject matter must not be contrary to public order, morality or causes serious prejudice to human, animal or plant life or health or to the environment. A few non limiting examples may further clarify the issues: (a) a process for cloning human beings or animals; (b) a process for modifying the germ line of human beings; (c) a process for modifying the genetic identity of Page 42 of 115 animals which are likely to cause them suffering without any substantial medical or other benefit to man or animal, and also animals resulting from such process; (d) a process for preparing seeds or other genetic materials comprising elements which might cause adverse environmental impact; (e) uses of human embryos for commercial exploitation*."

Thus, the patent claim examiner has to pay special attention while examining such patents to ensure whether the intended use of the invention will be solely commercial or morally & ethically degrading for plant, animal or human life. This is a reasonable step which would not hinder research and also keep a check on the intended use of such inventions. Public order and morality consideration play an immensely important role in determining the fate of an invention. To understand the same, it is critical to understand the jurisprudence behind such a constraint.

Public Ordre and Morality

The phenomena of morality are often associated with behavioral patterns and activities of individuals in a society. For ensuring compliance with a set standard behavior the society has divided every act in the shades of right or wrong which determine the morality of a person. These values are instilled for better and proper functioning.[75] It is believed that such an approach educates every member of that society by shaping their perceptions and institutions.[76] Public ordre on the other hand is derived from French law which entails any matter which raises concern or threatens to destroy the very fabric or a society.[77] However, this raises a query on thescope of public ordre and morality in Patent Law, and in order to understand this, there has to be a clear understanding of the concept, subjectivity and legality of 'morality'.

The Indian Patent Act 1970 contains the provision which specifically bars patenting of any invention the use of which is likely to be against public ordre and morality. Major amendments to the Act were brought about to comply with World Trade Organization's Trade Related Aspects on Intellectual Property Rights agreement. India being a member of WTO had to comply with the 'minimum standards' established by this agreement regarding protection of Intellectual property. For instance, product patents which were initially exempted from patent were brought under the ambit after the 2005 amendment to the Act.[78] Article 27 (2) of TRIPS states that:

"2. *Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect ordre public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law*."[79]

The same provision was adopted in the Indian Patents Act, 1970, in the year 2002, which provided for 'public ordre & morality' as a ground for constraint for patent grant. Patents, from the neoclassical economic theory angle, fulfil two pronged purposes i.e. it acts both as a reward to the inventor and an incentive to innovate. In the absence of patent in a certain field, investment will automatically flow towards other areas where there is potential to reap the rewards, thus widening the scope of research and development in the field. Other reasons based on public ordre and morality is regarding the very source or origin of these stem cells. Derivation of human embryonic stem cells is either from discarded or donated embryos or embryos generated from donated eggs. The process then follows the IVF, which has the potential to harbor these individual cells, which are capable of growing and division.[80] The concern from moral perspective lies in the fact that an embryo, even a discarded one, is considered a fetus when it goes on to survive between the 3rd to 9th months of pregnancy,[81] and is treated as a potential person, which is not to be harmed for cell extraction, thus restricting the procedure of derivation of cells.

Human beings are believed to be the greatest creation of God. Going against the germline genetic

identity will be to go against God's creation and bring forth something unnatural and against the human dignity,[82] for fulfilment of commercial interests, however beneficial it might be. Utmost regard has to be given to human dignity which cannot be compromised on the pretext of technological development. The same was explained in the case of *Kingdom of the Netherlands* v *European Parliament and Council of the European Union*[83] wherein the Court of Justice of the European Union stated that

"*The right to human dignity is recognized by nearly all Contracting States and also the ECJ as a fundamental right. The human body is the vehicle for human dignity. Making living human matter an instrument is not acceptable from the point of view of human dignity. The right to human dignity is perhaps the most fundamental right of all, and is nowexpressed in Article 1 of the Charter of Fundamental Rights of the European Union, which states that human dignity is inviolable and must be respected and protected."*[83]

Another concern that evokes the question of moral righteousness is pertaining to the ownership of these cells. It has been argued that a human being or any inch of humanbody cannot be "owned" by another like property. One owns one's own body and no one else's'.[84] Patents serve the society for its betterment and if the same have the potential of going against humanity, evolution of science will not serve as an exception to it.[85] While these are essentially borrowed legal principles from the domains of human rights legislations, they supplement the existing legal instruments in place, for the development of society and cannot be ignored for lack of any scientific evidence.

Conclusion

The jurisprudence of intellectual property primarily aims at balancing the monopolistic rights created in intellectual creations and the right of society at large to benefit from such creation. In order to achieve the said balance, most researchers restrict the discussions on economic argument, i.e. affordability and availability for the society to access the intellectual creation. However, the restrictions created by the clause of 'public ordre and morality' are a socio-political argument, which plays significant role in law making of the society. There are divergent views on the justification for patenting of stem cells which come around to the only factor for consideration being human betterment. Indeed, the potential benefits of these cells cannot be undermined but the same have to be viewed with the consequences that the society will reflect. A law which is in contravention of society's moral standards and are likely to disturb public ordre are bad laws. Therefore, an argument of blanket adoption of inventions related to life forms and its ingredients as patentable inventions would defeat the intended balance that IP jurisprudence wishes to achieve. In India, while the patent manual creates guidelines for examiners to reject the patent involving commercial exploitation of embryonic stem cells, however, in practice several patents have been grated on related subject matter. This creates a disparity in legal position and actual practice. Considering the same, the responsibility to clarify the situation after contemplating all the relevant factors, lies on the Patent offices, the legislature and the judiciary to provide clarity in the form of legal instruments which can be construed without any dilemma. It is, therefore, the responsibility on the state to take into account the arguments of all interest holders while enacting legislations and/or notifying guidelines for patent offices on the subject matter, and ensuring common practices throughout its jurisdiction. The very subject matter is so controversial in nature that one has to delicately resolve the issues surrounding it. Even a settled law on such a complex subject matter will have further socio-economic implications such as privatization and ownership of parts of human body, affordability of procedures, and secrecy on failed researches etc., thereby remaining unsettled in essence. Thus, there in an innate requirement of deeper research and knowledge in the area to be able to explore a balance between technological development which will benefit all and morality and will supplement the law.

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