STEM CELL PATENTING-LAW AND POLICY

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I Introduction

SCIENCE HOLDS enormous potential for new cures and treatments for a host of diseases, including diabetes, Parkinson's and spinal cord injury. Yet, the research is politically volatile and ethically sensitive because extracting the cells involves the destruction of a human embryo.

Every living thing is made of cells. The cell is one of the most fundamental units of life. Complex organisms such as humans are made up of millions of cells. In these complex organisms, the cells are organized into tissues, the tissues are organized into organs, the organs are organized into organ systems, and the organ systems are organized into the organism. Over two hundred types of cells make up the human body. These cells vary from blood cells to muscle cells to nerve cells. But as different as these cells are, they all have the same ultimate origin: the totipotent cells of the human embryo. These totipotent cells have the ability to form any type of cell present in the human body. Additionally, each totipotent cell is capable of developing into a complete embryo. In the course of normal embryological development, these totipotent cells give rise to genetically identical copies of themselves that, in turn, become the specialized cell types of the body by switching particular genes on or off. The process by which cells go from stem cells to specialized cells is known as differentiation.[1]

Embryonic stem (ES) cells are derived from these same totipotent cells of the early human embryo. Up to the eight-cell stage of development, each cell of a mammalian embryo is totipotent. The totipotent cells used to create ES cells are typically extracted from the inner cell mass of a day-five (postfertilization) human embryo known as a blastocyst, usually comprised of between two hundred and two hundred fifty cells. This extraction process renders the embryo nonviable. Rather than being totipotent, ES cells are pleuripotent: they can give rise to differentiated cell types from the ectoderm, the

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1. James J. McCartney, "Embryonic Stem Cell Research and Respect for Human Life: Philosophical and Legal Reflections" 65 *Alb L Rev* 600 (2002).

endoderm, and the mesoderm, the three primary germ layers of the embryo. During embryological development, the various cells of the human body arise from these three primary germ layers through further differentiation. This means that an ES cell can differentiate into almost all of the cells of the body. Human ES cells and human embryonic germ cells (EG cells) are the only known sources of pleuripotent human stem cells, leading many scientists to conclude that pleuripotent ES cells offer greater promise than alternative stem cell technologies such as adult stem cells or hematopoietic stem cells.[2]

In addition to being pleuripotent, ES cells are also capable of unlimited and undifferentiated proliferation in vitro. That is, ES cells, when cultured in the laboratory, will divide infinitely and will remain stem cells, as opposed to differentiating into specialized cell types. Human ES cells have been propagated in vitro for approximately two years and several hundred population doublings. This characteristic makes it possible to use one ES cell to create an ES cell line. A cell line is an unlimited source of cells of a standardized, genetically homogenous type. In other words, once you have one ES cell, you theoretically have an infinite supply of that ES cell that can be used for research, medical, or other purposes. These ES cell lines provide the human ES cells that researchers use for their work.

II What stem cells hold for future?

The intense interest in human ES cells comes from their potential medical uses. Because human ES cells are pleuripotent, they can theoretically be manipulated into any human cell or even into any human tissue. ES cells are viewed, therefore, as a potential source of replacement cells and tissues that could be used to repair damage caused by disease or injury.[3] For example, Israeli scientists recently announced that they had succeeded in transforming human ES cells into immature heart-tissue cells in their lab. It has been estimated that three thousand Americans die every day from diseases that may be treatable in the future with therapies derived from ES cell research.

There are also potential medical uses of human ES cells that do not involve transplantation. For example, human ES cells have been proposed as a way to study early events of human development. Another proposed use of human ES cells is to test therapeutic drugs and screen toxins.

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2. Peter Yun-hyoung Lee, "Inverting The Logic of Scientific Discovery: Applying Common Law Patentable Subject Matter Doctrine To Constrain Patents On Biotechnology Research Tools" 19 *Harv J Law & Tec* 88 (2005).

3. Amy Davis, "Patented Embryonic Stem Cells: The Quintessential Essential Facility" 94 *Geo LJ* 215 (2005).

Human ES cells also have potential use in developing new methods for genetic engineering. Perhaps the medical potential of ES cells was best summed up when former NIH director Harold Varmus, testifying on stem cell technology before Congress, stated: "There is almost no realm of medicine that might not be touched by this innovation."[4]

III Property rights in stem cells

British scientists have led the way in the field of stem cell research, thanks in part due to generous funding from the government and liberal licensing procedures. British laws allow licensed scientists to clone for human research purposes but not for the purposes of reproduction. In 2001, at a time when President Bush of the United States was hell bent upon starving the incipient stem cell research projects of federal funding, Britain had licensed cloning to create stem cells.[5] In that year, the UK introduced primary legislation against reproductive cloning but allowed scientists to use human embryos for a restricted range of research, specified by Parliament. This includes investigations into the therapeutic potential of stem cells, amongst other things. Since embryonic as well as adult stem cells displayed great therapeutic promise, research was intensified on both fronts simultaneously. These efforts bore fruit in May, 2005 when scientists were awarded Britain's first license for human cloning after successfully creating a cloned embryo.

The problems that property rights in the approved ES cell lines will create for researchers are already becoming clear. Officials from BresaGen, an Australia-based biotechnology company that has four human ES cell lines that qualify for government funding, recently announced that they will make BresaGen's ES cell lines available to academic researchers at no charge. These ES cell lines, however, will be far from free of cost. Allan Robbins, BresaGen's senior vice president and chief scientific officer, has explained that the ES cell lines will be made available to the researchers for "no upfront payment in exchange for some first right of refusal for any intellectual property that researchers invent."[6] Similarly, the Wisconsin Alumni Research Foundation (WARF), a company formed to patent research discoveries at the University of Wisconsin, Madison, has agreed to make its ES cell lines available to NIH researchers and researchers at nonprofit institutions

4. *Times of India* 15th Nov 2004.

5. The license was granted by Britain's Human Fertilization and Embryology Authority (HFEA). The HFEA is the UK's regulatory authority that regulates the use of stem cells from different sources by qualified and licensed scientists and researchers under controlled conditions.

6. *Supra* note 4.

that receive NIH grants for a nominal fee to cover handling and distribution expenses. However, WARF will retain all commercial rights to the materials.

The most valuable property rights that the owners of approved ES cell lines have are the intellectual property rights in the cell lines. It is these intellectual property rights that will most hinder ES cell science. Illustrative of the problems caused by intellectual property rights in the approved human ES cell lines is a patent owned by WARF, U.S. Patent No. 6,200,806 (806 patent). The inventor of WARF's 806 patent is Dr. James A. Thomson, a University of Wisconsin researcher who was the first individual to isolate human ES cells. WARF's 806 patent claims human ES cells with various enumerated characteristics, two methods for isolating human ES cells, and a cell line developed using one of the claimed methods. WARF clearly has full property rights, both personal and intellectual, in five human ES cell lines that it developed and that meet requirements for government funding. Based upon the eleven claims of the 806 patent, however, WARF is claiming intellectual property rights in every human ES cell line that qualifies for government/ federal funding although there may well be merit to that claim.

WARF's broad claims of intellectual property rights in the human ES cell lines has led would-be major players in ES cell science to scramble to negotiate with WARF. WiCell Research Institute, Inc., a company formed by WARF to handle its ES cell lines, and the Public Health Service (PHS) of the United States Department of Health and Human Services recently signed a Memorandum of Understanding (MOU) for research use of WiCell's (WARFs') existing patent rights and five human ES cell lines that are eligible for government research funding.

When ES cell science reaches the point where commercial medical products are ready to be developed and made publicly available, intellectual property rights will pose a formidable obstacle, spawning litigation that could delay medical applications of ES cell science. Illustrative of this is a suit recently filed in the United States District Court for the Western District of Wisconsin by WARF against Geron, a Menlo Park, California, biotechnology company that was WARF's partner in the research that led to the 806 patent. In this suit, WARF and Geron are wrestling for control over commercial rights to develop products from cell types that can be made from human ES cells. Geron holds exclusive commercial rights to WARF's patent rights and approved ES cell lines to develop products from six cell types, including nerves, liver, and heart muscle. Geron also has an option to add exclusive commercial rights to twelve more cell types that it wishes to exercise. WARF has sued Geron to block Geron's exercise of that option. Every cell type to which Geron holds an exclusive commercial right is, of course, a type that WARF is not free to commercially license to other

entities. This is very high stakes litigation. Somewhere down the road, the scope of WARF's 806 patent will probably also need to be litigated.[7] All of this litigation slows down ES cell research and wastes resources that could be devoted to furthering that research. Needless to say this has caused a lot of heartburn among various civil rights groups as private companies are creating monopoly rights over things created using public research.

IV Ethical and moral issues pertaining to stem cell research

Along with the incredible medical potential of human ES cells, however, comes a catch: serious ethical and moral concerns over human ES cells that arise from ES cells' origins. Current techniques for deriving human ES cells require extraction of cells from a human embryo, which leaves the embryo nonviable. This fact has lead to widespread and outspoken opposition to research using human ES cells from, among others, pro-life groups and the Catholic Church. [8] Their argument against ES cell research is analogous to their argument against abortion and that is life begins at conception, so the destruction of an embryo in the process of creating human ES cells is equivalent to killing any other human being.[9]

As against these ES cell opponents, the chief proponents of ES cell research have been patients' groups representing individuals inflicted with the maladies for which ES cell technology seems to hold the most promise. The most notable ES cell proponents are Nancy Reagan, lobbying on behalf of Alzheimer's disease patients such as President Ronald Reagan; Christopher Reeve, lobbying on behalf of victims of spinal cord injuries; Mary Tyler Moore, lobbying on behalf of diabetes patients; and Michael J. Fox lobbying on behalf of Parkinson's disease patients.

These groups' argument for human ES cell research is as follows: the sacrifice of an unwanted human embryo is justifiable if done for the benefit of human beings suffering from maladies treatable by ES cell-derived techniques. This argument is echoed by some legislators who insist that supporting the destruction of human embryos for the purpose of developing lifesaving medical treatments is, in effect, a

7. Christopher R. Carroll, "Selling The Stem Cell: The Licensing of The Stem Cell Patent and Possible Antitrust Consequences" *U. Ill JL Tech & Pol'y* 441(2002).

8. Damon J. Whitaker, "The Patentability of Embryonic Stem Cell Research Results" 13 *J Law & Pub Pol'y* 377 (2002).

9. Stephen S. Hall, "Adult Stem Cells" *Tech. Rev.* Nov. 42-44 (2001) *available at* http://www.techreview.com/articles/hall1101.asp.

"prolife" position. Another point that proponents of ES cell research emphasize is that the embryos used to create ES cell lines are typically surplus embryos that were created by in vitro fertilization for reproductive purposes and are no longer needed. Because these embryos, if not implanted, will simply be destroyed, many question the harm in using them to benefit others. The recent advent of embryo adoptions, however, has removed some of the poignancy from this point.[10] While the number of excess embryos is currently far greater than the demand for embryo adoptions, some have predicted that the current ES cell controversy will lead to a bridging of that gap.

Opponents of ES cell research counter with the fact that ES cells' medical promise is currently unproven.[11] This argument leaves ES cell researchers in a quandary: researchers cannot get funding because ES cells' medical promise is unproven, and researchers cannot prove ES cells' promise because they cannot get funding. President Bush summarized the ethical and moral concerns surrounding ES cell research well when he broke them down into two questions: "First, are these frozen human embryos human life, and therefore, something precious to be protected? And second, if they're going to be destroyed anyway, shouldn't they be used ... for research that has the potential to save and improve other lives?" For politicians to get involved in the stem cell research controversy is indeed unfortunate, because in places like the United States with an anti-stem cell research President in place, the fructification of political views into legislations results in a virtual straight jacketing of further research into the subject.[12]

V Political dimensions of stem cell research

President Bush as well as the Republican Party in the United States have consistently opposed embryonic stem cell research and have consistently threatened to cut off federal funding for such projects- a move that could prove disastrous for stem cell development. Also in support of a moratorium on embryonic stem cell research is a diverse

10. Groups, such as Nightlight Children Adoptions' Snowflake program in Fullerton, California, are springing up that link infertile couples to couples that have excess embryos from IVF treatments. The excess embryos are implanted in the donee mother and, in successful cases; the result is pregnancy and a child.

11. John Miller, "A Call To Legal Arms: Bringing Embryonic Stem Cell Therapies To Market" 13 *Alb LJ Sci & Tech* 583 (2003).

12. Stem Cell Research: Hearing Before the Committee on Appropriations, Senate Subcommittee on Labor, Health, and Human Services, Education and Related Agencies, 106th Cong. (1999) (statement of Maria C. Freire, Ph.D., Director, Office of Technology Transfer, National Institutes of Health), *available at* http://www.hhs.gov/asl/testify/t990112a.html

coalition consisting of conservative Christian groups (including the Catholic Church) as well as right-wing political formations. This formidable combination has traditionally sought to hold the 'moral high ground' on issues such as abortion and stem cell research, arguing for the ending of both practices. The democrats on the other hand are by and large in favour of greater federal funding for stem cell research and see in it the possible dividends to millions of patients suffering from 'incurable' and 'life-threatening' diseases. A variety of other liberal outfits also support the democrats' stance on the issue.[13]

In 2001, President Bush cut off federal funding for embryonic stem cell research, limiting it only some 70-odd stem cell batches in existence then. This has proved a controversial move, especially since other nations such as the UK, Sweden, Belgium, Israel, South Korea and even India have been far more liberal and supportive of such efforts by their respective scientists and researchers. Recently, the US House of Representatives voted in favour of federal funding for embryonic stem cell research despite President Bush threatening to use his presidential veto to stop it from becoming law.[14] Supporters of the bill claimed it would accelerate cures for diseases while opponents predictably viewed it as akin to abortion. President Bush, while disapproving of the action of the lower house, claimed that his steadfast opposition to stem cell research funding arose from the fact that providing federal funds for the project would be creating "…new incentives for the ongoing destruction of emerging human life."[15] One of the major and most controversial issues in the area of stem cell research thus involves the moral status of the embryo and whether it is inviolable or whether it should be available for experimentation. In all fairness, the only true statement that can be made is that people on both sides of the great divide created by stem cell research believe in the sanctity of life; only the scope differs:[16]

> In the complex debate over embryonic stem cell research, we must remember that real human lives are involved, both the lives of those with diseases that might find cures from this research and the lives of the embryos that will be destroyed in the process.

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13. White House Press Release, Fact Sheet, Embryonic Stem Cell Research *available at* http:// www.whitehouse.gov/news/releases/2001/08/20010809 -1.html

14. "US Lower House defies Bush, okays stem cell study funding," *The Times of India,* 21 May 2005. The House approved the motion by a 238-194 vote. This was however less than the two-thirds majority that would be needed to override a Presidential veto.

15. *Ibid.*

16. *Supra* note 13.

Fortunately, in the US there are currently no limits on private funding of human ES cell research. Scientists working with private funding are free to conduct whatever research they want on whatever ES cell lines they want. So one might wonder as to why the question of federal funding for human ES cell research is proving to be such a pressing concern? Government funding is critical to ES cell research both pragmatically, because it provides necessary resources, and symbolically, because it places the significant weight of the government behind the research. Although private funding for human ES cell research should be increasingly forthcoming as ES cell science comes closer to reaching its potential, at this early stage of ES cell research, government funding is imperative for significant progress. Public (government) funding is, therefore, absolutely crucial to ES cell science's success, even in the US. It provides necessary pragmatic and symbolic support for the research and subjects ES cell science to a degree of government control, which, if properly exercised, will benefit ES cell science.

VI Benefits of stem cell research

People don't die of old age; they die of diseases of old age. Stem cells are the most promising way of attacking old age diseases as they are regenerative and specialise in any kind of tissue. May be stem cells will lead to life-extension and if it happens, we can't stop it... - John Harris, Founder-Director, International Association of Bioethics.

Stem cells are the master cells of the human body and can divide to produce copies of themselves as well as varieties of specialized cells. They are found in various parts of the human body and at every stage of development from an embryo to an adult. There are two main sources of stem cells-adult and embryonic. Embryonic stem cells, taken from embryos that are just a few days old, can be turned into any of the 300 or so different types of cells that make up the adult body. Of the two main sources of stem cells, embryonic stem cells are considered to be more versatile and scientifically useful. The two main sources of embryonic stem cells are human embryos left over from a fertility treatment and those cloned in the laboratory. Since stem cells are so inherently versatile, they could be potentially used to repair and replace damaged human tissue. Stem cells are expected to cure a variety of diseases, from Parkinson's disease to cancer. [17]

Every major disease is the result of a genetic problem. That problem can be solved with mutated cells derived from stem cells. For instance,

17. Advanced Cell Technology's (ACT) website *available at* http://www.advancedcell.com/ht-program.html. For updates concerning activities ACT refers to as "Human Therapeutic Cloning."

patients who are diabetic can have a functional pancreas thanks to stem cells. Ignoring the UN's ban on the cloning of embryo's the UK Government has backed research on stem cells by setting up a UK stem cell bank.[18] This national stem cell bank is the first resource of its kind in Europe. It was set up with support from the UK Government as well as the Medical Research Council and today is a model of successful cooperation and participation between the government and the medical community. The researchers are not using cloning to make babies. Instead, they create test-tube embryos to supply stem cells, the building blocks which give rise to every tissue in the body and which are a genetic match for a particular patient, preventing rejection by the immune system. The Newcastle Fertility Centre in the meantime has patented the six lines isolated from an embryo that can be used in a regenerative process, and is justifying the patent by arguing that it would bring in additional sources of income that can in turn be ploughed back for research purposes. In addition, the centre has promised to publish its works and allow scientists and other individuals access the same for basic research purposes.

Stem cell researchers are not cloning the embryo but a group of cells after fertilisation, so the fears over the procedure are unfounded. The intense interest in human embryonic stem cells comes from their potential medical uses. Because human stem cells are pleuripotent, they can theoretically be manipulated into any human cell or even into any human tissue. With South Korean scientists now claiming to have successfully cloned patient-specific stem cells,[19] it is now possible to imagine a future in which the root of all the diseases plaguing mankind can now be identified and tackled. All of a sudden, new vistas have opened which, if successfully pursued, could result in a revolution in the way we view and treat diseases. Given below are some common 'new age' diseases that afflict people and the favourable impact on their lives that stem cell research holds out for them:

Parkinson's disease: Parkinson's disease occurs when certain neurons in the part of the brain called the *substantia nigra* are impaired. These cells produce a chemical known as dopamine, which allows coordinated functioning of the body's muscles and if impaired, causes slowness of movement, rigidity, and tremors. Scientists are attempting to revitalize the damaged brain cells and reverse the disease. Cell replacements through transplantation are also being experimented with. Gene therapy

18. The UK has reason to feel satisfied with the efforts of the State-sponsored Newcastle Fertility Centre that was set up with an investment of 30 million euros. The Centre has so far managed to isolate six concerned lines from embryo which can now be grown into skin cells and nerve cells among others.

19. *Supra* note 17.

has enormous potential since it could result in the development of 'viruses' that can be engineered to deliver genes that increase the supply of dopamine or promote regeneration of neurons thus effectively bringing a halt to the spread of the disease.[20]

Diabetes: The disease is characterized by abnormally high levels of sugar and glucose in the bloodstream. Diabetes occurs when the islet cells of pancreas are destroyed and stop producing insulin; or when the body cannot use insulin effectively enough, leading to complications including blindness, kidney failure, heart disease, etc. In Japan, transplantation of pancreatic cells from a live donor- from a mother to a daughter has been done to free the latter from insulin dependency. A major breakthrough that is being anticipated with the advent of gene therapy involves predicting the disease on the basis of genes, and then assessing the complications arising therewith. This is in addition to the possibility of human embryonic stem cells being developed to differentiate insulin-producing beta cells in the body of the recipient and thus reverse the spread of diabetes.

Alzheimer's disease: This is a progressive brain disorder that slowly destroys memory and thinking skills and eventually the ability to carry out even simple tasks. This deadly process, once begun, is irreversible. Many existing forms of treatment for the disease have not proven very effective, thus the emphasis for a breakthrough in stem cell research. Gene therapy has the capability to be successful here as well. Scientists have shown that skin cells from patients suffering from Alzheimer's can be taken and then modified to secrete a protein found in healthy brains called the nerve growth factor, which maintains the health of the nerve cells. The cells can then be implanted into those degenerating areas of the brain among sufferers of the disease. Clinical trials have revealed that the rate of degeneration of the brain cells have considerably reduced as a result of this type of treatment.

Heart diseases and cancer: Heart disease is the biggest killer in the world today. Cardiac arrest is caused by rapid fluttering and pumping of the heart resulting in death that can occur within an hour of developing complications. Stem cell research in this area attempts to prevent the blocking of ventricles and perform the job being done by 'balloon therapy' and new age stents. Cancer is also another major killer, a cure for which may be tantalisingly close thanks to the advancements in stem cell research. The DNA of a cell directs all its activities, so damage to DNA is responsible for the creation of cancer cells. Gene therapy uses a retrovirus[21] to repair the damaged gene.

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20. *Ibid.*

21. A retrovirus is a term used to describe a virus that incorporates its own DNA into that of a host cell.

Adult stem cells have been used for years to treat leukemia and other forms of cancer, and this has opened up new avenues for stem cell therapy. Cancer cells are eliminated by using infection fighting proteins and cells known as antibodies and T cells.[22] Scientists are now attempting to extract these T cells from the body, produce them in huge quantities and then replace them in the body.

Cloning: Human cloning will lead to huge benefits for childless couples and would prove extremely useful for those people who cannot produce their own sperm or eggs. Besides, with advances in stem cell research and cloning, two gay men can become father and mother of a baby born out of their own cells as synthetic gametes can be directed to either sperm or egg from the same stem cell source. Thus, same sex couples can have their very own biological child. Today, one still requires a women's uterus to carry the embryo, but once the artificial lab wombs become a reality, even this will not be necessary. [23]

Questions still remain however, over the efficacy of cloning. Many ethical campaigners argue that cloning of human cells for any purpose should be banned since even legitimate research involving cloning could be hijacked to create multiple copies of a person. Experiments in animals have also shown the technique to be far from perfect with many cloned animals being born with abnormalities. Opponents of cloning state that similarly, there is no way to ensure that the birth of a child with defects and genetic abnormalities after the cloning process can in any way be prevented. A counter argument to this is that natural reproduction and reproduction through cloning are "two equally imperfect methods" since even in normal sexual reproduction, there is an 80% failure rate.[24] Thus, it is argued that though both systems are now quite susceptible to failure, with infusion of greater funding and research, reproduction through cloning can prove to be ultimately more efficient and safer.

VII Indian story: Going from strength to strength

Stem cells are increasingly used for treating diseases like osteoporosis, diabetes, benign tumours, hepatic and renal failures and even find use in treating congenital disorders like autism and there are

22. Antibodies only attack the cancer cells. This solves the problem of the healthy cells being destroyed with the use of more conventional techniques such as chemotherapy.

23. Roger Brownsword, "Stem Cells and Cloning: Where the Regulatory Consensus Fails"39 *New Eng.L. Rev*. 555 (2005).

24. Views expressed by John Harris, Founder- Director of International Association of Bioethics *Times of India*, 15 Nov 2004.

efforts now being made to make the same facilities available to people in India. India has the highest number of annual births worldwide and has promise of the largest supply of cord blood in the world. The Health and Family Welfare Minister recently stated that the government was planning to bring in a legislation to preserve human stem cells for curing many degenerative diseases by using the same for organ culture. The need to stop the wastage of stem cells by setting up a stem cell bank in the country was stressed,[25] as was the need for creating a conducive atmosphere to ensure the development of generic medicines and the conduct of clinical trials. Unlike other governments, the Indian government has been wholly supportive of efforts at stem cell research.

As far as the medical community is concerned, India is lucky to have it complementing the government in its efforts to promote stem cell research. The Indian Council for Medical Research's (ICMR) draft guidelines for stem cell research in 2004 specifically state that although there must be a regulatory apex body for monitoring purposes, sources of stem cells can include those derived from foetal tissue. The preamble to the guidelines is in itself an indication of the nation's will to be a world leader in this field. It states, "the profound characteristic of a stem cell is its capacity for extensive self-renewal and retention of multilineage differentiation potential. Recent research suggests that human stem cells can give rise to many different types of cells, such as muscle cells, nerve cells, heart cells, haematopoietic cells etc, giving the hope for major advances in health care. The era of clinical marrow, tissue and organ transplantation is poised for breakthrough with the possibility of stem cell transplantation and therapy. Realizing the potentials of this new technology in modern therapeutics and biomedical research it is strongly recommended that stem cell research and its clinical applications should be promoted in the country…" More than 15 labs in the country are involved in this work and a Rs. 500 crore department of biotechnology budget, of which 30% is allocated for stem cell-related study,[26] There was more good news when recently, Histostem- a well known South Korean biotechnology company that is engaged in developing human cell-based therapy and expressed interest in setting up a stem cell bank in India.[27] The company has developed the technology of mixing cord blood for transplantation to adult patients and is looking to make this treatment available for patients in India as

25. The Health Minister observed that annually there were more than 25 million births in the country and that if not properly utilised, all the umbilical cords generated would simply go to waste.

26. "Biotechnology Boom" *The Hindu* 25 May, 2005.

27. *The Economic Times* 9 Jul 2005.

well. India is certainly exhibiting the potential to become a global hub for this kind of research. Thus it can be seen that India has, by and large, been very supportive of stem cell research. Some are even optimistic enough to suggest that the biotechnology boom could result in India being a nucleus for stem cell research.

VIII Latest developments: Nobel – for stem cell research

Recently, scientists in South Korea have used a method called therapeutic cloning to produce stem cell lines that are generic matches to their patients. This research marks major strides in work aimed at making it possible one day to transplant healthy cells into humans to replace cells damaged by spinal cord injuries, diabetes, Parkinson's and other diseases. It represents a major advancement in the quest to grow patient's own replacement tissues to treat diseases. Besides, the identical DNA make-up of the cells means that they will not be rejected by the immune system of the body.[28] The first successful cloning of human cells required 242 egg cells to create one "line",[29] but by refining laboratory techniques, the South Koreans have made eleven new lines of embryonic stem cells using only 185 egg cells- representing more than a ten-fold improvement in efficiency. Thus, what the study undertaken by the South Koreans shows is that the stem cells can be made that are specific to the patients regardless or age or sex and that these cells are identical genetic matches to the donor.

The method for the extraction and subsequent use of these cells is relatively simple. First of all, the nucleus from the patient skin cell is removed. The nucleus from the patient egg cell is also removed. These initial stages involve the transfer of genetic material from a non-reproductive cell of a patient into a donated egg from which the nucleus has been removed. Next, the skin cell nucleus taken from the male is implanted in the egg cell from the female's body. The hybrid cell is then stimulated to grow, until it becomes a nearly featureless ball of about 200 cells, known as a blastocyst. The early stage embryo or the blastocyst grows and the inner cell mass yields stem cells genetically identical to the patient from whose cell the initial extraction has been done. Lastly, the human embryonic stem cells are removed. Stem cell lines, such as those developed in the UK and in South Korea, can be

28. "South Koreans created tailor-made stem cells," *The Times of India*, 21 May 2005. Subsequently it was disputed and discredited and admitted by the researcher.

29. When cloning of human cells was first attempted in 2004, it required 242 egg cells to make microscopic embryos, which could create a single batch or "line" or cells.

used for disease research.[30] Stem cells, in theory, can also be prompted to grow into any of the body's cell types. However, this aspect is still under examination by scientists and researchers.

A bit of good news that has recently emerged has been the fact that an alternative to controversial embryonic stem cell technology has been discovered. Scientists in Singapore have recently claimed to have discovered an easy source of stem cells-the outer lining of the umbilical cord. Many see this as an alternative to the embryonic stem cell technology that has caused much controversy in places like the United States and Western Europe due to the fact that it involves destruction of the embryos. Scientists claim that the outer lining of the umbilical cord (amniotic lining) possesses stem cells that are not only easily accessible but also possess both epithelial and mesenchymal cells (which are responsible for producing every cell in the body). The supporters of this new technology believe that a large number of stem cells can be easily obtained from a part which is medical waste. Besides, it is urged, no conceivable ethical issues can be raised in opposition to such a procedure. This is indeed a revolutionary discovery that could forever change the contours of cell research. If this gain can be exploited in time and the results of the experiments live up to expectations, it could actually lead to eliminating the "moral and ethical questions" involved in stem cell research forever.

Stem cells are of vital interest to researchers because they can be developed into any kind of functioning cell in a living object. The Swedish Royal Academy while announcing Nobel prize for Chemistry for the year 2006 to Kornberg of Stanford University said of the sometimes politically controversial process that- "Understanding more about how transcription is regulated is therefore one of the necessary steps, if we want to realize the full potential of stem cells in medicine."

Understanding transcription also is vital to the development of treatments using stem cells. "Knowledge about the transcription process is also fundamental for understanding how stem cells develop into different kinds of specific cells, with well-defined functions in different organs, "the Royal Swedish Academy added in its citation. It is indeed very gratifying to note that the Royal Academy has chosen Prof. Kornberg for his significant research in stem cell technology which would go a long way in promoting advance research in this area.

Kornberg was the first person to create an actual picture of the transcription process at the molecular level, in the important group of organisms called eukaryotes which, as opposed to bacteria, have well-

30. Researchers at Newcastle (UK) have managed to develop six stem cell lines so far, while their counterparts in South Korea have been successful at developing eleven new lines of embryonic stem cells.

defined cell nuclei, Mammals, as well as ordinary yeast, belong to this group of organisms.

James A. Thompson's (of Wisconsin Alumni Research Foundation) isolation of Human E.S. Cells in 1998 set off a big effort to turn basic technology into treatment for various diseases. This is viewed as the first major step to isolate the human ES cells and grow them in culture and was heralded as one of the greatest scientific discoveries in history. Some scientists complained that the Wisconsin patents are too broad and the University's enforcement efforts impeded research. The Geron Corporation which financed some of Thompson's Research projects has exclusive commercial rights to heart, nerve and pancreatic cells derived from human E.S. Cells.

The US patent and trademark office has recently made a preliminary decision to reject three fundamental patents on human ES cells. If the decision stands, it will definitely loosen restrictions on research in a promising new field.