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Abstract

The stem cell therapy is called the preventive remedial medicine for those who in need of transplantation. The therapy focuses on the cells that are reproduced from the patient's body or from the another donor's body to replace the damaged cells or tissues that form the human organ. This therapy has demonstrated a huge leap in recent years, which has provoked a juristic and legal controversy upon its use and acquisition of patent ownership, where these difficulties cannot be eschewed unless there is a special legislative system regulating this therapeutic procedure.

Keywords: Creativity, Patent, Stem Cells, legislative system. Medical Treatment:

I. Introduction

The stem cell sources may vary according to their use in treatment, where the most important sources are the bone marrow, umbilical cord at birth and embryonic stem cells but these cells are treated in medical laboratories to be preserved and stored in specialized banks against a certain fee. The use of stem cells may result in several relevant legal formalities and medical assets that physicians should adhered when adopting such modern technology not to mention the intellectual property rights that have become dominant mechanisms for being used in innovation policies, particularly, in modern medical sciences. The challenges related to competing models in innovation policies have fully emerged in line with the methods existed in other sciences. Thus, stem cell science is consistent with the emergence of such patents, and that the nature of this modern therapeutic medical technique has provoked a debate about intellectual property rights, which require consideration the complex methods of stem cell science and its development. Eventually, the science can be systematically utilized in the light of issuing regulations and laws regulating thereof, instead of its flexibility that may allow all to employ it without rules to protect its ownership. Therefore, this study focuses on the nature of stem cells, the extent of acquiring its inventors a patent and make use of it, the

public take advantage of it and stay away from monopoly by major investment companies.

II. The legal nature of a patent ownership for stem cell therapy.

The stem cell therapy is deemed a modern medical measure that has been developed through the technical and medical processes by expert persons in such a modern medical technology. The stem cell therapy invention that requires a patent by developing its guidance as a modern technology based on innovative idea and industrial applicability of the developed therapeutic medicines and any invention that meets the traditional conditions of industrial applicability, novelty and inventive steps can be granted a patent, whether the invention is novel in its industrial products or innovative ways (Black, 1989, p.5).

A. Definition of Stem Cells:

The naming of stem cells has varied among users of such modern, that called the master cells, stem cells and embryonic cells but eventually end up in one meaning and are used for one purpose as well as exploited in various ways.

1. Concept of Stem Cells:

It is called embryonic stem cells in master cells, with the ability to divide and grow up to give various types of specialized cells that give any type of cells under certain physiological and experimental conditions to become therapeutic cells with specialized functions in treatment of muscle and liver and other uses. (Idris,2006.p:9943) The stem cells are the fundamental component of renewable tissues which are impartial cells with the ability to divide and grow up to give different types of specialized cells[(1)].(Jilam,2004) By itself, stem cells are not considered a human organ, but ccollection of tissues in turn forms a human organ that performs certain functions. Consequently, the legal provisions of human organs and its transplantation on their constituent tissues cannot be applied, otherwise, the diverse medical research has become in stalemate, particularly, there are many legislations that prevent the medical research on organs (Sarhan,2011.p:182) and other legislations impose restrictions and conditions should be followed when conducting therapeutic medical research.

([1]) Othman al-Jilam, Wonder of guilt, the origin of Man who does not wear out, the seventh conference of scientific miracles in the Quran and Sunnah, Dubai 2004, www.alargam.com retrieved on 9/10/2018

2. **Purpose of using stem cells**

It is required to obtain, use and dispense the stem cells a therapeutic justification, medical necessity or scientific research need provided that comply with the laws, regulations, instructions and legal provisions governing the subject matter. Also, the patient's interest in medication, importance of scientific experiments and necessity condition are all justifications that eventually subject to the conscience of physicians and researchers and the extent of their obedience and adherence to the instructions, customs, ethics of medical profession and scientific research[(2)]. The legitimacy of using stem cells may be raised when it has been obtained by the legal means stipulated by regulations for the use of stem cells[(3)].

B. **Stem Cell Therapy Acquiring a Medical Patent**

A patent is a deed granting its owner, under certain conditions, a legal protection against commercial investment for his invention by other researchers. while the researcher or beneficiary, seeking to get specific benefits from this invention, should obtain the permission from the proprietor.

1. Limits of medical intellectual property for stem cell therapy

The recent developments of medical inventions in the stem cells have had a significant impact on the local intellectual property rules inside the developing countries, which could hinder research on critical diseases through authoritarian practices of the developed countries to register genetic resources patents without prior arrangement with the developing countries and utilize this knowledge commercially.(Miller,1994.p:31.41.343)

The World Intellectual Property Organization (WIPO) seeks to further harmonization of the patent system that replaces TRIPS Agreement, while there is a constant pressure on the developing countries to raise the levels of intellectual property protection in their systems, based on standards applied in developed countries[(4)]. There is compelling

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([2]) Article 7 of the Jordanian Stem Cell Regulation states that: The acquisition, use and disposal of stem cells requires a genuine medical or therapeutic necessity or research need, in accordance with the provisions of the Islamic Sharia and the applicable medical norms.

([3]) Article 9(a) of the Jordanian Stem Cell Regulation.

([4]) Report of the United Nations Conference on Trade and Development (UNCTAD) 1996, TRIPS Agreement in Developing Countries, Geneva, United Nations Development Program (UNDP), Human Development Report 2001,http://www.undp.org/hdr2001

evidence that intellectual property has been vital in promoting invention in the pharmaceutical industry. The granted monopolies are one of determinants of the patent protection power and departure from the scope of legal protection, the patent owner has the rights to use the genetic knowledge other than those specified in the patent including information that was disclosed by someone else later.(Miller,2006.p:9943)

2. Ownership of therapeutic innovation in stem cells

Many countries, adopting such type of treatment, have witnessed a boom in the use of such a technology. So, there is a great fear of granting several patents, which means the emerge of monopolies relating to this type of treatment, which in turn will raise a great concern and wide debate on the impact of such type of patents on the fate of the modern art in terms of research or exploitation thereof commercially. (Idris,1994.p:17)

The acceleration of these developments in the medical sciences of stem cells emphasizes that we have seen the receptiveness of other mental ideas from human creativity through the results of basic laboratory research towards development of marketable products for human use making the developed future guaranteed. The upscale creativity in the development of stem cells may be a positive interaction of mutual large number of genes by introducing them into separate relationships achieving the therapeutic purpose and that accomplishes the highest of creativity that acquires the right to retain in intellectual property. (Yahya,2008.p:38)

This new technology needs a large amount of money to conduct a research, which affects the social contract entailing increasing the treatment charges derived from the genes and the purchasing power of individuals, which may lead to unjustified monopoly of the owner of the invention, in addition to the moral problems that may result from its use, especially when getting them from the human body and preventing of trafficking stem cells. The problems have been reflected at the legal level, although some countries have been interested in regulating access to them and how to preserve them, but these laws are insufficient to protect them in classification of the inventor's findings as an easy treatment among members of society, drawing the attention that under the provisions of the conventions on intellectual property, patents on any invention, whether a product or industrial processes and in the therapeutic fields, can be obtained provided that they are new, include inventive step and usable in therapeutic industries without considering the place of invention or technology whether is imported or local product, provided that this invention does not violate the public order and the protection of private life or human health.(Regenberg,2011.p:79-84)

III. Legal basis of ownership of stem cell therapy

The position of the national and international legislation on the acquisition of the patent ownership of stem cell therapy has differed, some countries agreed so by imposing certain restrictions, while others disagree human exploitation in medical treatment operations.

A. Position of domestic legislations from the ownership of a medication by stem cells.

The patent is considered a social contract between the inventor and society, through gaining profits resulting from the invention and the medical creativity, in turn, the society should benefit from medical production and social interest.

1. The position of Jordanian legislation on the ownership of stem cell therapeutic patent.

Jordan is one of the pioneers in the treatment of chronic diseases through utilizing stem cell technology, it has devoted a series of special legislation governing the use, how to deal with the parties, storage process, dispensing and issuance of civil liability for the risks entailed, such as a use of stem cells regulation No. 14 of 2014, collection bases of stem cells from umbilical cord instructions No. 2 of 2014, the amended instructions for stem cell insurance No. 1 of 2014 and Stem Cell issuing from stem cell bank Instructions No. 6 of 2014. The purpose of the Jordanian legislator is primarily to control scientific research and treatment using human stem cells extracted from human embryos. Such regulations and instructions are the first of its kind in the Arab region, while Jordan is one of few countries in the Middle East that has enacted laws to protect the participants in clinical trials. The latter law should act as an example for other countries in the region.

The new laws prohibit the private companies from using human stem cells in research or treatment and shall be allowed using them only by government institutions or government-funded academic institutes in Jordan, which have higher levels of transparency than private companies and are subject to the supervision of the Ministry of Health and a specialized committee in this regard.

It is worth mentioning that the human bone tissues have been successfully processed in the cell therapy center at the University of Jordan[(5)], and will be used in the next few days. This achievement is the result of four years of continuous research, whereas this tissue will benefit many bone diseases such as bone cyst, unhealed fractures and loss of some parts of bone. In addition, such tissue accelerates bone healing and recovery the patient.

([5]) Article published in the Jordanian newspaper, Al–Rai, 10/3/2015, p. 6.

It is proved that the therapeutic use of bone marrow transplants, including blood-producing stem cell transplantation in Jordan, and such procedures are already regulated under laws and regulations in pertaining the medical practice. The new law therefore poses a clear distinction between these techniques and human embryonic stem cell therapy, as this law does not only cover all current aspects of the stem cell research and its uses, but also allows for further amendments in future. It requires the formation of a national committee that will, inter alia/ along with its others tasks, be responsible for enacting special laws, this to maintain the stem cells in special banks in line with international standards, without considering the ownership of patents for such a kind of technology. With referring to article 3 of the Jordanian Patent Law, the patent shall be granted for each new invention resulting from an innovative idea and an innovative improvement of an invention protected by a patent in all technical fields, while each of which are based on a scientific bases, and industrial applicability with regard to stem cell.

2. The position of foreign domestic legislation

The United Kingdom, United States, Australia and Canada have supported conducting research on human therapeutic and reproductive cloning experiments, as well as embryonic stem cell therapy trials. Such countries have issued legal texts dealing with using stem cell research[(6)], in Australia, in 2001, the government approved a unified act allowing the reproduction of treatment by human embryo cloning for medical purposes.(Sarhan,2006.p:182)

It is worth mentioning that most European countries, such as Italy, Norway, France and Germany and the World Health Organization (WHO) oppose cloning for human reproduction; however, allow therapeutic cloning and use of stem cells, even if the consequent loss of the part used for treatment.(Aldiyat,1999.p:201) If this subject matter is acceptable to these countries, it is unacceptable in the Arab countries, Islamic Sharia and any other country that prohibits the use of stem cells in case it results loss of used part in treatment.

The US patent system has also granted biotechnological patents since the seventies of the last century on Deoxyribonucleic acid (DNA). Since 1980, patents on microorganisms, cellular genes and stem cell strains have become a focal point of that era where thousands of patents have been granted despite the opposition of US jurisprudence to such inventions on living substance before that year.

The possibility of granting a patent on stem cells is a realistic fact in the United States of America, therefore, the biotechnology investors want to acquire legal protection for

(6) French journal, Le Monde, published on 4/10/2002, and published on the newspaper's website: http://www.lemonde.fr/. retrieved on 20/6/2016

inventions that can be reached by stem cell researches, University of Wisconsin, for instance, has been granted several stem cell patents. As long as, such patents are related to the product, they include all its branched products and all methods and means that allow to obtain patent from the primary products.

The remarkable development of stem cell use, at all levels, may ultimately lead to an evolution in the research process constituting a hindrance to the therapeutic research and commercial exploitation. This raises the concern of granting many patents on therapeutic drugs derived from genetic cells affecting the difficult competition between inventors and tinkering with identifying the competing products, which means prolonging monopolies over valuable medicines.(Lemley,2006.p:128)

The French legislator included the provisions related to patents of biotechnology field in the intellectual property law in line with the provisions of the European Directive through providing the traditional conditions of granting patents of living matter representing the creativity and industrial applicability. However, the legal bases that should be taken into account are the privacy of genetic research before starting the legal procedures necessary to protect the potential rights to obtain a patent. Furthermore, the French law also requires applying a compulsory licensing regulation, upon the request of the Minister of Health, on inventions in medical treatments when the public interest so requires.

B. The position of the International legislation on the ownership of stem cell therapeutic patent.

The legal provisions for conducting research on human embryos are considered very rare at the international level.(Sherif,1988.p:343) There are several legal provisions dedicating the right to life in general, for example, article (3) of the Universal Declaration of Human Rights of 1948, article (1) of International Covenant on Civil and Political Rights of 1966 which entered into force in 1976, and some regional human rights agreements such as the US agreement which entered into force in 1969 [(7)] which states protect life as of the date of pregnancy in article 4 thereof.

Although some international provisions generally addressed the freedom of scientific research, for example; article 12(b) of the Universal Declaration on Human Genome and Human Rights adopted by UNESCO in 1997, states: "- b. Freedom of research, which is necessary for the progress of knowledge, is part of freedom of thought. The applications of research, including applications in biology, genetics and medicine, concerning the human genome, shall seek to offer relief from suffering and improve the health of

(7) Article 4 of the American Convention on Human Rights states: "Every person has the right to have his life respected. This right shall be protected by law and, in general, from the moment of conception. No one shall be arbitrarily deprived of his life."

individuals and humankind as a whole." Article 14 of the said Declaration stipulates that: "States should take appropriate measures to foster the intellectual and material conditions favorable to freedom in the conduct of research on the human genome and to consider the ethical, legal, social and economic implications of such research, on the basis of the principles set out in this Declaration." Also, article 10 of this Declaration has developed an ultimate restriction on the freedom of scientific research in the field of the human genome, states as follows: "No research or research applications concerning the human genome, in particular in the fields of biology, genetics and medicine, should prevail over respect for the human rights, fundamental freedoms and human dignity of individuals or, where applicable, of groups of people."

At the European level, the Council of Europe adopted in 1997 the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Applications of Biology and Medicine, but this convention did not resolve the possibility of conducting research on the embryo. Article (15) of this Convention enshrines the principle of freedom of scientific research in the field of biology and medicine, subject to the provisions of this Convention and other legal provisions that secure a protection of the human being .(Idris,2006.p:9943)

As for conducting research on human embryos, the Convention has left the matter to the States member as a result of the great differences among them in this matter to regulate the possibility of embryonic research in their domestic legislation. However, the Convention imposed two basic conditions on States, as follow: firstly: prevent the development of human embryos for the purposes of scientific research, secondly: Enact legal rules that provide adequate protection for the embryo.

The European Commission has issued the ethics of science and new technology opinion No. 15 of 14/1/2000 pertaining to the ethics of conducting research on human stem cells and their uses, which stated that it is morally unacceptable to develop embryos based on a donor's gametes in order to obtain embryonic stem cells. On 30/9/2002, the European Union decided to suspend research funding on human stem cells until December 2003 in the sixth Framework Program for Research and Technological Development (FP6) for the period between 2003 and 2006. The European Union would propose common rules to be applied to fund such research and access to a patent that its benefits could be utilized for the interest of public.

Conclusion

Stem cells are an important source of many innovative medical treatments and have been widely utilized at both international and domestic levels. Many countries have embraced the idea and worked to regulate it legally with regard to how to make use of it, use and maintain without addressing to grant such technology a patent to ensure respect and invest thereto to disclose its results for public.

This modern technology needs a deed to be protected to become an organized therapeutic process accessible to all individuals. The stem cell therapeutic invention produces a specific profitable outcome, this should be by utilizing and investment legitimately for the benefit of mankind. This requires a national and international legislator and the competent authorities recognizing the rights of the invention’s owner and issue a patent certificate according to a specific legal system.

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