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Chapter

# Patentability of the Human Embryonic Stem Cell Lines: A Legal and Ethical Aspect

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## Abstract

In this study, patentability of the human embryonic stem cell lines has discussed in the legal and ethical perspectives. In vitro human embryonic stem cells can be defined as body parts that are departed from the body. Human embryonic stem cell lines are constituted of differentiated self-renewal pluripotent stem cells, which means they have no characteristics to become a human-being. However, interpreting the terms like human embryo and right to property widely can cause the human embryonic stem cell lines are misunderstood as unpatentable. For our point of view, giving the human embryo the protections of both personal rights of the donor and the right to property of the owner of the invention does not reduce the legal/moral status of the human embryo. Besides, the obligations which these rights imposes to their owners, such as the principle of human dignity and prohibition of financial gain can protect the human embryo in a better way.

**Keywords:** human embryonic stem cell lines, patentability, human dignity, personal rights, right to property, prohibition of financial gain, law, ethics

## 1. Introduction

Human embryonic stem cell researches (HESCRs) has been widely discussed in different perspectives. In this chapter, the issue will be considered from the perspective of the patentability of the human embryonic stem cell lines (HESCLs). Embryonic stem cells are derived from the inner cell mass of an embryo in the blastocyst stage. Embryonic stem cells are "pluripotent" cells, which means, they are, technically, differentiable into a wide range of cell and tissue types [1]. The researches on human embryonic stem cells have the potential to discover and develop treatments for a variety of diseases including Alzheimer's disease, diabetes, neurodegenerative disorders, heart diseases, Parkinson's disease, or anemia [1, 2]. HESCLs make scientific researches and stem cell treatments possible by producing differentiated self-renewal pluripotent stem cells. However, conflicts of interest arise between patients seeking treatment and human embryos from the fact that, while harvesting HESCs, the human embryo is destroyed.

The subject of patentability of the HESCLs has also been discussed because of the legal prohibition of financial gain on the human body and its parts and the principle of human dignity [3]. It is not possible to accept human embryo and HESCLs as a property that is suitable for industrial applicability when the concepts

are regarded with their traditional definitions. The principle of human dignity and the prohibition of financial gain on the human body and its parts prevent such acceptance. However, the human embryo and the stem cells derived from it have a *sui generis* legal and moral status. Besides, in the patentability of the HESCLs issue, the patentable thing is not the human embryo itself, but the pluripotent cell lines differentiated into self-renewal pluripotent stem cells and the method of the process.

In the first part of this chapter, the *sui generis* legal status of the human embryo will be discussed by interpreting the legal status of the human body parts. In the second part, conditions of patentability will be analyzed from the perspective of the patentability of the HESCLs. Finally, in the third part of this chapter, the patentability of the HESCLs will be viewed in the moral and ethical aspects.

## 2. Legal status of the human embryo

It is possible to make an interpretation based on the legal status of the human body parts to understand the legal status of the in vitro human embryonic stem cells. Such an interpretation needs a few definitions and premises:

1. We can define human body parts as the body parts of a person.

2. Human body parts can be divided into two such as inter-body parts (which are in a unity with the body) and the body parts that are departed from the body [4].

3. It is possible to divide human cells into two such as somatic cells and germ cells.

4. A human embryo is a being that is composed of germ cells of women (OVAs) and men (sperms).

5. A human embryo can be in vivo (in the body of the pregnant woman) or in vitro (in the outside of a woman's body, probably in a Petri tube).

6. Human embryonic stem cells are derived from the inner cell mass of an embryo in the blastocysts stage [1].

7. Embryonic stem cells are "pluripotent" cells, which means, they are, technically, differentiable into a wide range of cell and tissue types [1]. However, they are not "totipotent" cells. A basic meaning of this fact is: they cannot differentiate into a human embryo; they can only differentiate into specific types of cells and tissues [5].

8. Since we agree with the general acceptance of the human embryo has no legal personality, we are in the view of human embryonic stem cells of an in vivo human embryo is within the body parts of the pregnant woman.

However, things are much more complicated in the subject of the in vitro embryo. Does it belong to the donor of the ova or the donor of the sperm or both of them? Does it belong to the patient of assisted reproduction treatment? What happens if it is donated for the researches? Does it belong to the researcher? What does "to belong to" mean for human body parts? Does it mean ownership? Is it possible to accept human body parts as properties?

According to the traditional definition, the right to property is a right, which gives its owner the authority to use, to enjoy the fruits and the ownership. If one of these three authorities not legally enjoyable for a person, then that person has no right to property on that property or that thing is not subject to the right to property. Authority to ownership means legal availability to buy and sell. Authority to ownership is not enjoyable for body parts because the prohibition of financial gain on the human body and its parts is a fundamental principle, which is accepted worldwide in both international and domestic regulations. Article 21 of the Convention on Human Rights and Biomedicine (CETS No. 164) with the title of "*prohibition of financial gain*" is a good example of such regulations by saying "*The human body and its parts shall not, as such, give rise to financial gain*" [6]. Another example is Article 3 of the European Union Charter of Fundamental Rights. According to the article with the title of "Right to the integrity of the person,"

1. *"Everyone has the right to respect for his or her physical and mental integrity.*

2. *In the fields of medicine and biology, the following must be respected in particular:*

   - *the free and informed consent of the person concerned, according to the procedures laid down by law,*
   - *the prohibition of eugenic practices, in particular those aiming at the selection of persons,*
   - *the prohibition on making the human body and its parts as such a source of financial gain,*
   - *the prohibition of the reproductive cloning of human beings"* [7].

Because of the prohibition of financial gain on the human body and its parts, according to the general view in the French, German and Turkish doctrine, germ cells that are departed from the body cannot be considered as property, and giving harm to these cells causes a violation of personal rights, not of the right to property [4, 8–13]. While some of the authors claim that protecting human embryos is possible only with the personal rights of the donors [8–10] others emphasize its *sui generis* legal status [11–13].

As it is seen while the doctrine agrees with the view of human embryos have a sui generis legal status and can be protected with the donor's personal rights, there is no unity in the view of it is also possible to protect the right to property to the human embryos. As we mentioned before, it is possible to make an interpretation based on the legal status of the human body parts to understand the legal status of the in vitro human embryonic stem cells. Because human germ cells are about reproductive rights, more specific protection is provided for the germ cells than that of the somatic cells. Because the human embryo has characteristics of both the donors' and the embryo itself and also has the potential to develop into a living human, more specific protection is provided for in vivo human embryo (for example with abortion laws) than that of the germ cells. On the other hand, such a more specific protection is not provided to in vitro human embryo, although it has the same characteristics as in vivo human embryo. From our point of view, protecting it with the right to property besides the protection of personal rights can give the more specific protection the in vitro human embryo needs.

## 3. The patentability of HESCLs from the legal aspect

A patent is a legal document, which provides a right to enjoy the innovation's owner and prevent third parties from violating the rights of the owner. The owner of the patent has the opportunity to declare the rights related to the patent to third parties [14]. By giving patents, states aim to encourage scientists to make science. An innovation that is given patent improves the scientific development of societies by presenting the innovation to the memory of the society. States target community development by authorizing exclusive competence to the owner of the innovation [15].

Legislations which affect the patentability of HESCLs usually regulate the patentability of the biotechnological inventions field, in which the applications about the HESCLs take part. Unfortunately there is no legislation regulates the patentability of the HESCLs specificly. For this reason, rules for the patentability of the HESCLs are reachable by interpreting legislations on the biotechnological inventions. Therefore, in this part of the syudy, patentability criteria and international regulations on the biotechnological inventions will be examined in the first two subtitles. Then, in the third subtitle of this part, patentability of the HESCLs will be specificly considered.

### 3.1 The relationship between biotechnological inventions and patentability criteria

Patents are qualified with three criteria. To an application is being patented, it has to be novel and inventive and have industrial applicability [16]. These criteria are also needed for the patent application in the field of biotechnology. However, because of the sui generis characteristics of biotechnological researches, some differences appear. In the paragraphs below, the affection of the sui generis characteristics of the biotechnology field on the meaning of the patentability criteria will be explained.

Novelty, which is the first characteristic of patentability, means going beyond the state of art in the field of biotechnology [17]. To a research in biotechnology is beyond the state of art, it has to be about a technic that is more developed than the technic that was known before. It is not enough the research itself has the ethical values that are determined by the international organizations, the novel technic should also be compatible with these values. The qualification on the novelty in the field of Biotechnology is not far more different from the qualification on the novelty in the other fields. However, in the field of biotechnology, there has to be a specific qualification, since in these innovations the materials existed in nature are mentioned. The fact that proteins, genes, enzymes, and such materials are already existed in nature and in the researches such materials are processed, the characteristic of novelty does not appear traditionally. For this reason, in the field of biotechnology studying more on material or finding the different physical characteristics and forms of the materials do not eliminate the innovations characteristic of novelty. Also the fact that its benefits are already known does not eliminate the characteristic of novelty [18]. However, if the subject of the patent application has the same technic with the technics that are already known, it is accepted that the application has not got the characteristic of novelty, without considering its production method.

The second criteria for a patent application is its inventiveness. A patent application should be inventive. In this context, firstly, the target of the application should be determined. If there is a determined target for the application and if this target is reachable with the estimated theory and the existing information for

the application, it is possible to say that there is an innovation. Another matter, which proves that there is an invention, is the application is capable of fulfilling the existing needs. Besides, there should be a reasonable expectation for the technic to be "obviously" successful, which means each time the technic has used the consequences should be the same. No application that has obvious consequences can be patented [19].

PharmaStem v Viacell Case of United States District Court of Delaware is an example of the conflicts on inventiveness in Europe. The case is about an invention on an isolated DNA molecule, which codes human tissue plasminogen activator (t-PA). The court has decided that producing human t-PA by using human recombinant DNA technology is an obvious consequence for any expert in the field. The court says that, oligonucleotide probing was a known technic, any expert could reach the consequence of the invention that seeking for the protection of patent because choosing oligonucleotide probs did not need a high level of skill and experience. According to the court, the monopoly rights given to the patent owners provide much more than a prize given for winning the race of recombinant expression of the gene. For this reason, the court says that the invention seeking patent protection could not succeed in the criteria of inventiveness. It is seen that the court has emphasized the obviousness of the isolation methods of DNA, not the structure of the molecule, and reached the conclusion of the decision should be made by considering the creativity of the method, not by considering the speed of the method's application [16, 20]. As is seen, the criteria of inventiveness qualified specially in biotechnological researches.

The last criteria for a patent application is industrial applicability. Determination of the industrial applicability can be hard for a biotechnological invention because, in general, it is not as clear as for an invention on a gene or a protein sequence, as for the inventions in other fields of science. For example, in genetic researches, short DNA sequences' or expressed sequence tags are used as probs. However, some quarters claim that expressed sequence tags do not have enough benefits for patentability [16].

A patent application, when it is considered with the knowledge that is widely known, should include a real industrial applicability expectation, instead of a completely theoretical probability of industrial applicability. Without a clear description related to its method or describing the method without pointing out one of its practical benefits, it is not enough for the industrial applicability criteria to succeed. It is also not enough to relate the structure to some reachable but undetermined theoretical aims for the industrial applicability criteria to succeed. However, having no experiment or laboratory data related to the method of the application seeking patent protection does not show that it is not reaching the industrial applicability criteria. Criteria of industrial applicability cannot be dependent on experiments or laboratory data. It is enough to give a reasonable and reliable benefit or estimated data. Reliability can be supported by the possible information that can appear later. Because laboratory reports, expert opinions, and clinical trials related to the invention increase the reliability of the applicability of the invention, they support the industrial applicability criteria indirectly [21].

It is possible having no industrial applicability criteria for one part of the invention to affect the industrial applicability criteria of its other part. For example, when a part of the invention is about receptor, if the receptor has no industrial applicability, the agonist (compounds forming reaction in the cell by connecting to the cell receptors) related to the receptor also have no industrial applicability. Likewise, a method, which defines an agonist related to a receptor, has no industrial applicability, either. On the other hand, it would not be possible to say that the receptor, agonists, and the method of defining the agonists do not have the criteria

of industrial applicability if, for example, it is clarified with some in vivo or in vitro data in the description that it is about the treatment of obesity [16]. To sum up, the situation of a part of the application is the lack of the criteria of industrial applicability does not mean that the whole application is not patentable. Hence, the effect of technological developments on the criteria of industrial applicability increases in each passing day.

### 3.2 Patentability of biotechnological inventions in international conventions

In this part of the study, international regulations on the patentability will be discussed. In this context, The European Patent Convention and The Agreement on Trade-Related Aspects of Intellectual Property Rights are important for regulating general criteria for patentability and its exceptions. Directive on the Legal Protection of Biotechnological Inventions is especially related to the subject of our study by regulating the general rules and exceptions of the patentability of stem cells.

The European Patent Convention [22] (Convention) makes giving valid patents in the state parties possible. Although there is no specific regulation on the patentability of biotechnological inventions, it is possible to conclude by analyzing its general provisions. To an invention is patentable in the context of the Convention, it should have the criteria of novelty, inventiveness, and applicability in industry. In the article 53 of the Convention, the unpatentable inventions are counted. According to article 53/a the patent protection cannot be provided to the inventions which violate ordre public and morality. In the article 53/b, it is regulated that the patent protection cannot also be provided to "*plant or animal varieties or essentially biological processes for the production of plants or animals*". Finally, according to the article 53/c European patents cannot be granted to "*methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practiced on the human or animal body*".

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIP's) is another international agreement on patentability. In the article 27 of TRIP's limits for the patentability of inventions are regulated. The article is important for having wide coverage for the protection granted with patentability. According to the article, nearly all inventions, without considering its place, its ability to export or its technological area, are patentable and thereby they can be released into commercial circulation like the other trade objects. However, there are some exceptions to this wide regulation, too. The most important exception which is also essential for the biotechnological inventions is "ordre public and morality". This regulation of the TRIP's has parallels with article 53 of the Convention. Both regulations need reconsidering because the concepts of ordre public and morality are open to interpretation. In this interpretation biotechnological developments should also be considered [15].

Another international agreement in which the patentability of biotechnological researches and especially stem cells are regulated in Directive 98/44/EC of The European Parliament and of The Council of 6 July 1998 on The Legal Protection of Biotechnological Inventions (Directive). The Directive is criticized for including uncertainties and gaps. The Directive's attribution of being blocked off in a matter of confliction in which it should be clarified causes difficulties in interpretation. For this reason, modern technologies and necessities should contribute to the interpretation of the Directive.

The term "biotechnology" which appears in the title of the Directive and constitutes its target means, application of industrial and commercial processes on a biological material (living cells and microorganisms) with scientific methods.

This definition matches up with the definition in article 2 of the United Nations Convention on Biological Diversity [23] dated 1992. Because the investments in the field of biotechnology have high risks, the investors and owners of the inventions need to have legal protection and the preventions against them to be removed. So, the target is regulating the limitations on biotechnological material, especially on scientific researches related to the human body; not constituting a new and special kind of patent for the field of biotechnology. By regulating the limitations, it is aimed at both supporting biotechnological developments and reaching a level of development proper to public order and morality which is regulated in domestic and international regulations [24].

In the Directive, while the prohibited and conditioned subjects are determined, it is also regulated whether biotechnological inventions are patentable or not. According to article 3(2) of the Directive, biological materials are patentable if they are isolated from their natural environment. The article regulates that, "*The human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions*". However in the second paragraph of the same article says that "*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, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element*". According to article 6 of the Directive,

> "1. *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.*
>
> 2. *On the basis of paragraph 1, the following, in particular, shall be considered unpatentable:*
>
> a. *processes for cloning human beings;*
>
> b. *processes for modifying the germ line genetic identity of human beings;*
>
> c. *uses of human embryos for industrial or commercial purposes;*
>
> d. *processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes.*"

As it is seen, ordre public and morality are also regulated in the Directive as limits of patentability of biotechnological inventions. Cloning human beings, modifying the germ line genetic identity of human beings, uses of human embryos for industrial or commercial purposes, and modifying the genetic identity of animals are accepted to be out of the patent protection.

The problem in the patentability of HESCRs is the Directive's tendency to use the term "human embryo". However, the term "human embryo" is not defined in the Directive. This situation causes the term human embryo to be widely interpreted as if it is the same thing with pluripotent cells of the human embryo. In fact, embryonic stem cells are "pluripotent" cells, which means, they are, technically, differentiable into a wide range of cell and tissue types [1]. However, they are not "totipotent" cells. A basic meaning of this fact is: They cannot differentiate into a human embryo; they can only differentiate into specific types of cells and tissues [5]. So, in the HESCRs pluripotent stem cells are used, processed, and human embryonic stem cell lines are

produced. Neither pluripotent stem cells nor the human embryonic stem cell lines are the same thing with human embryos. Besides, it is not possible for both of them to be used for producing or cloning human embryos. Pretending as if they are the same thing with the human embryos causes the patentability of human embryonic stem cell lines to be trapped into the discussion of the destruction of human embryos for research purposes which is another, but not the same, side of the story. As it is seen, when the knowledge learned with modern technology is not gathered with the regulations written before by the way of interpretation, the regulations cannot succeed in their aims.

As an example of the problem mentioned above, the European Court of Justice has decided in its Oliver Brüstle v Greenpeace eV. case (dated 18.10.2011, numbered c-34/10) that an application is unpatentable by interpreting the term of human embryo widely, in the context of article 6(2)c of the Directive. When the case is analyzed, it is seen that the Court has considered the principle of human dignity and the prohibition of commercial use in its decision. However, interpreting every patent application related to HESCRs within the contexts of human dignity and commercial use would cause a broad interpretation which is contrary to the aim of the Directive. Surely, human dignity is a fundamental principle, which should be considered in every legislating and interpreting process and the Directive serves for human dignity with all of its existence. However, both the Directive and the other international regulations on the matter also aim to support the researches to find treatments for severe and life quality reductive diseases such as Alzheimer's, pancreas cancer, blindness, and Parkinson's. For this reason, terms like human dignity, human embryo, or commercial use should not be interpreted in a way to cause go far from the total target. Preventing inventions with cruel commercial and industrial purposes and presentation of such inventions to the use is a noble cause which should be granted with legal regulations. However, steps to this cause should not be stopped from preventing human suffering. HSCRs need large amounts of economic resources. In order to that economical resources are granted, and researches are developed, patents are very important. The fact that an invention has an economical value should not shadow its necessity for the sake of humankind. However, to maintain the necessities of human dignity, the opportunity for each human being to reach such inventions in an equal way should be granted in the legal regulations.

### 3.3 The effect of the protection of the absolute rights on the patentability of the HESCLs

The sui generis legal status of human embryo basis on the characteristics of the ability to develop into a living human being, a person [4]. Because of this sui generis legal status and developments in science and medicine especially in the field of stem cell science, new interpretations on the right to property appeared. According to such interpretations, it is possible to provide human embryos the protection of both personal rights and the right to property. Providing the protection of the right to property besides the protection of personal rights do not decrease the legal status of the human embryo that of the property [4, 25]. On the contrary, providing extra protection increases the legal status of the human embryo [26, 27]. However, if these cells will be used as a continuation tool of the donor's personality with the assisted reproductive technologies' help it is better not to entitle them the legal status of the property [25]. In order to the subject of patentability of HESCRs is understand better, in this part of the study we will clarify the terms of personal rights and right to property, which are the branches of the absolute rights, the subjects of these rights, and the necessities of these rights for the patentability.

Absolute rights are the rights that give its owner the broadest power over the owner's own personality and the property they are subject to. Everyone must respect these rights and obey the limits drawn by them. In this respect, absolute rights are powerful rights that can be claimed against every third person. Personal rights are a type of absolute rights, which arise from being a person and they are a tool for the protection of the human embryo. With these rights, which cannot be waived, transferred be converted into money and can only be subject to a claim for compensation in case of violation, it is desired to protect the person's material and moral existence.

As it is mentioned before, HESCs are body parts that can be departed from the body and they include their donors' personal data. For this reason, personal rights of the donors' need to be protected in the HESCRs. It is important to protect the personal data with personal rights against the interventions of the third parties. In his scope, personal data of the donors are under the protection against revealment and unauthorized use with the domestic and international regulations. Oviedo Convention [28] is a good example for such international regulations. According to article 5 of the Oviedo Convention;

> *"An intervention in the health field may only be carried out after the person concerned has given free and informed consent to it.*
>
> *This person shall beforehand be given appropriate information as to the purpose and nature of the intervention as well as on its consequences and risks.*
>
> *The person concerned may freely withdraw consent at any time."*

Article 22 of the Convention is also important for the subject of this study. According to the article 22, "*When in the course of an intervention any part of a human body is removed, it may be stored and used for a purpose other than that for which it was removed, only if this is done in conformity with appropriate information and consent procedures.*" If we interpret the articles for the case of HESCRs, we can say that before the human embryo is or the ova and sperms to constitute the human embryo are taken from the donors, the informed consent of the donors should be taken. The informed consent should include the purpose, process, and possible conclusions of the intervention. If the purpose of the intervention was, for example, treatment of assisted reproduction but the purpose has changed after having surplus embryos and the experts are willing to use the surplus embryos for HESCRs, they should take a new informed consent from the donors and clear the target, process and possible conclusions of their new purpose, too. As it is seen, it is not possible to accept the patent application for HESCRs if the application includes HESCs that is taken without the donor's informed consent. And if such research is done, the personal data of the donor will be protected with his/her personal rights [29].

As the personal rights of a person are protected against the interventions of the third parties, they are also protected from the person's him/herself. The inalienable characteristic of personal rights requires the prevention of gaining economic benefits from the human body parts by the rule of the prohibition of financial gain. As it is mentioned above, it is not possible for a person to sell his/her body parts for research and therefore, such research would be unpatentable. Human body parts of the donors- for our case of study their human embryos or HESCs- are protecting as being their personal data with their personal rights. The restriction of having financial gain from the person's own body parts is a necessity of human dignity.

The right to property is also claimed to be a tool for protecting departed human body parts. The right to property is one of the absolute rights. Absolute rights can

be divided into two, such as; absolute rights on tangible properties and absolute rights on abstract entities. Absolute rights on tangible properties are rights that give its owner direct control over the property and such rights can be claimed against everyone. Absolute rights on the abstract entities are defined as intellectual property rights. The intellectual property rights are the rights of individuals regarding their thoughts, intelligence, knowledge, and feelings. They are the rights of the products in the field of art, literature, law, or science. Such a right to property is not constituted on the product, it is directed on the intellectual property which has a legal entity independent of the product itself. Both property rights on the tangible properties and the intellectual property rights provide a superior power of protection to its owner. In the HESCRs, the object of the patent application, the object that the right to property is wanted to be constituted on, is not the body part of the donor. The object of the patent application to which the protections of the right to patent is wanted to be granted is the method or the HESCL which is produced as a conclusion of the application of the method. So, it is not possible to the right to property is constituted on a body part. Besides, HESCs themselves is not patentable since such an object of the patent application would not have the criteria of novelty and inventiveness. The thing that makes HESCs patentable is the technic, the scientific method applied to it.

It is possible to mention intellectual property rights in the patentability of the methods of the HESCRs. However, in the patentability of the HESCLs, since the object of the patent application is the stem cell line which is produced as the consequence of the research, a property right on the tangible properties should be mentioned. While the right to the property gives several rights to its owner, it also imposes several obligations. In this scope, the kinds of embryonic stem cells that the right to property can be constituted, the techniques that can be patented, and the ways that the patents can be used should be evaluated under the obligations imposed by the right to property. One of the obligations imposed by the right to property and thus the patent is that a legal act contrary to ordre public and morality should not be protected by the legal system. For this reason, with this obligation imposed by the right to property, the patent owner cannot act against human dignity while exercising his/her rights [29].

To sum up, HESCs, which are a kind of body parts that can be departed from the body, can be protected with both personal rights and the right to property. The protection granted with personal rights is for the favor of donors. This protection appears by both taking their informed consent and prohibiting the financial gain. However, the right to property is for the favor of the owner of the invention. With the right to property of the owner of the invention, the technique he/she applies on the HESCs and/or the HESCLs produced as the consequence of the technique are protected. So, the object which provides financial gain and the right to property will be constituted on is the technique of the owner of the invention and/or the HESCLs produced as a consequence of the technique. Another value that should be considered is the principle of human dignity. It is possible to prevent the patent applications contrary to human dignity, with the restrictions provided by the personal rights and obligations imposed by the right to property. By giving the patent right for the HESCRs, this researches will have economic support, which will help the development of science. This way, there will be an opportunity to find and develop the treatments of severe human diseases.

## 4. Ethical/moral discussions on the patentability of the HESCLs

Ethical debates on both HESCRs and the patentability of the HECSLs find their basis in the debate on the legal/moral status of the embryo. We have mainly

discussed the approaches to the legal status of the embryo in the first part of the study. The subject of legal status of the human embryo is mostly related to the ethical questions that arise due to the destruction of the embryo by HESCRs. In this part of the study, we will first consider ethical debates on stem cell discussions in general and then ethical debates on the patentability of the HESCLs based on these discussions.

The basis of the views which claim that HESCRs are unethical is the acceptance that the embryo is a part of human development. According to such views, embryo stage, which is a part of human development such as the stages of fetus, baby, child, old age, is also a humanbeing and is under the protection of human rights. Using the human embryo to treat diseases is the instrumentalization of humans. However, human should be an end, not a tool. This view may be called as "nongradualist position" [30].

It is clearly seen that the Kantian understanding of morality underlies this view. According to this, human beings are dignified and have certain rights due to their potential to be an intelligent and autonomous creature [31]. For the same reason, the embryo deserves the protection of human rights due to its potential to be a creature with intelligence and autonomy, just like other people who are lack of intelligence and autonomy. This view, in the discussion of Kantian moral philosophy, which will be discussed below, adopts the idea that the embryo does not have to have reason and autonomy, therefore, having this potential is sufficient to benefit from the protection of human rights [32].

The second argument in the debate about the status of the human embryo is that the human embryo is a creature to be protected and respected, but does not have the quality of a fully developed baby. The moral status of the embryo increases with its development. Once formed, it gains the right to be protected as a human and to have rights. In this mode of understanding, the moral status of the embryo is not absolute but related to other moral elements. So it is at a relative level. When it comes to the possibility and benefit of other people's treatment, the moral status of the embryo at a certain stage of development is decided by comparing it with this benefit. If the benefit to be achieved is a state of "goodness" that is superior to the destruction of the embryo, then destroying the embryo is not considered wrong. This argument provides an ethical opportunity for HESCRs [33].

Another question that needs to be answered after the question of whether the human embryo has the right to life is whether the human embryo is a carrier of human dignity. The main issue here is whether it is possible to talk about human dignity where there is no human life. For example, if we do not accept the embryo's right to life, will we be able to honor it? In the doctrine, it was argued that the right to life and human dignity should be evaluated separately. It has been determined that there is human dignity wherever there is human life, but it cannot be said that there is no human dignity where there is no human life. However, the reason why the human embryo is honored here is because the dignity of the potential future person is preserved [34].

In another view, which describes the relationship between human rights and human dignity in a similar way and is based on the idea that the right to life and human dignity can exist independently, a distinction is made between respect for human life and the right to life with regard to the status of surplus human embryos. The human embryo is respected in terms of respect for human life. The right to life, on the other hand, is evaluated independently of this respect and is recognized gradually depending on passing certain stages. The result of this is that in some cases the general well-being outweighs the respect for the life of the human embryo. However, according to this opinion, the fact that the embryo can be sacrificed for the good of the society does not mean that the human embryo

is not honored. Even if the human embryo does not have the right to life, it has honor. This view is based on the assumption that the benefit of humanity is superior to respect for the life of the human embryos that will be destroyed under any circumstances and is criticized by its opponents as being consequential [35]. This view has also been criticized for its contradiction. It was stated that if the life of the embryo is respected, human rights should be given to it. It has been argued that the solution to this complicated issue would only be possible if the in vitro fertilization method is limited with fertilizing the OVAs that will be transferred to the uterus. Only in this case the human embryo is not instrumentalized and human dignity will be preserved [36], which is not possible for the current level of development of the assisted reproductive techniques.

John Harris, on the other hand, argues that the embryos that occur due to the in vitro fertilization method or miscarriages should be used instead of being wasted. He bases this thesis in the "Waste Prevention Principle". The other option, which is wasting the resources, argues that there are very strong moral reasons for using these resources for a useful purpose. He states that if the surplus embryos are already going to be destructed, it is not wrong to use them for a good purpose. He goes one step further and claims that organ transplantation from a fetus subjected to abortion is not different from organ and tissue transplantation from a cadaver [37].

Among the views which claim that HESCRs are supportable, there is another view that refers to the fact that the right to life is not an absolute right and that restrictions can be placed on this right in order to find treatment for incurable diseases. The basis of this view is the acceptance that the human embryo is a human and has the right to life. The view suggests that there is a conflict of interests between the right to life of the human embryo and patients seeking for treatment and in this conflict of interests finding treatment for severe diseases can be preferred [38].

The topic is getting a little more complicated in therapeutic cloning. Because, unlike the case of harvesting HESCs from surplus human embryos, in the therapeutic cloning the human embryos are created only for the purpose of harvesting HECSs. While the using surplus human embryos derived from the in assisted reproductive treatments is still discussive, it is claimed in the doctrine that creating embryos only to use them for therapeutic HESCRs or treatments of patients is much more problematic in the ethical aspect. In the initial phase of this technique, the nucleus removed from the patient is transferred to the OVA and a human embryo is created. The created human embryo however, is not transferred to the uterus and is used to obtain HESCs. Since the embryo has nearly the same genetic characteristics with the patient who will benefit from the HESCs, it is used in the treatment of the patient's diseases and in the process of organ formation for transplantation to the patient. The main problem in therapeutic cloning is that the human embryo is formed to be destroyed for the treatment of another person's diseases. In other words, the human embryo is produced to be destroyed for the benefit of another person or society.

According to the views that oppose to the therapeutic cloning technique, even if it has a therapeutic aim, this technique makes the embryo only a tool for the treatment of another person, and moreover, to know that the embryo will be destroyed at the very beginning of this process means the denial of any value of human life and accordingly the violation of human dignity [36]. As mentioned earlier, it has been suggested that the embryo can be attributed to pre-life dignity from the view of it has a potential to become a fully developed human being. However, in cloning for therapeutic purposes, the human embryo will not be able to benefit from honor protection retrospectively as the human embryo was not

created to become a human being. In other words, since the human embryo does not have the characteristics of a fully developed human being, its dignity will not be violated [39]. In this context, we need to evaluate whether the embryo is dignified or not according to Kant's ethics, which is our mainstay of human dignity. First of all, it has been claimed that making a differentiation between human dignity and the right to life made in German Law in order to protect dignity in terms of embryos and the dead was incompatible with Kant's understanding of human dignity [40].

The view of the human embryo does not have human dignity is referred to by many authors by referencing the views of Kant. According to this, it is said that the embryo should not be honored as it does not have the characteristics of being self-aware, taking responsibility for its actions, acting independently, based on Kant's grounding of human dignity within the framework of moral autonomy. However, this view was opposed, and it was argued that Kant did not connect human dignity to actions and fulfillment of these acts. According to Kant, anyone who has the capacity to act morally should be considered as an honored person in an experimental manner. Every human being has the capacity to take moral action that comes from being human. In Kantian ethics, human dignity is a concept which belongs to the imaginable world (the universe of noumens). Since honor belongs to the imaginable world and has a super-experimental quality, criteria such as brain activity belongs to the world of phenomena (universe of phenomena), life capacity outside the mother's womb should not be taken into account. The embryo should be dignified from the moment of fertilization. According to this view, although the human embryo cannot use its capacity to act morally, it has been said that it should be regarded as an honored person because it has this ability [40, 41].

However, in the doctrine, there are views which also claim that it should be discussed briefly whether therapeutic cloning is an ethically problematic technique or not because finding treatments for severe human diseases is also a noble aim which serves to the human dignity. According to this view, in the therapeutic cloning, it is aimed to create a somatic cell or tissue type from another somatic cell. The fact that a step for this method is creating a human embryo and destroy it to harvest HESCs should not affect the whole purpose in a bad way. The created human embryo was a somatic cell which is processed to become another human cell, tissue or organ type, which means it was never going to be a fully developed human being. Indeed, the hope for finding and developing treatments for severe human diseases is an important and unignorable necessity. For this reason therapeutic cloning technique which is legally accepted in some states such as United Kingdom and Holland deserves to be discussed without pretending as if it is the same thing with reproductive cloning which aims to produce human beings [42].

When the human dignity is violated is another point that should be mentioned. Human dignity becomes meaningful as an absolute law, as the human beings see themselves as an end and treat all other people in the same way. It goes beyond trends, personal qualities and acquires a universal quality. Just as we cannot hold the person who is used as a tool legally responsible for a passive act carried out by destroying his will over another; likewise, we cannot hold people responsible for their actions against their wills. Conversely, man is responsible for what he does, not what he suffers. However, by acting contrary to the value of her/his own species, of which a she/he is a member, she/he can act inappropriate to her/his own human dignity. The prerequisite for being understood with human dignity and its being so valuable seems to be protected by a good understanding of this value and thus by considering it with this understanding and valuing it at least as much as the value it finds in its own person. In this context, any interference with the possible right to life of the embryo, regardless of whether it human dignity or not, can be regarded

as a behavior that violates human dignity if it can be considered as a behavior contrary to the value of the species of which a human being is a member.

All these debates also constitute the basis for the debate on the patentability of the stem cell. According to our point of view, it would be appropriate to evaluate the ethical discussions about patentability of the HESCLs in the same way the discussions on HESCRs are evaluated. So it would be meaningful to divide the topic of patentability of the HESCLs into two such as the patent applications that use surplus human embryos for their methods and the patent applications that create human embryos for their methods.

The first criticism of the patenting of HESCLs is that the human embryo has been instrumentalized, made into something tradable and of commercial value, just like the HESCRs. However, as mentioned in the previous sections, the subject of the patent is not the human embryo or HESC itself, but the processed state of the HESCs taken from in. In other words, it is not possible to patent the human embryo.

This criticism should be considered separately in terms of the therapeutic cloning method, which includes the process of destroying the human embryo produced for the treatment of another person. As it will be remembered, this method was subject to heavy criticism that the human embryo, which has a life potential, would be instrumentalized in the production process, since human embryos were produced for the treatment of another person. If this view will be supported, the criticism that the human embryo is instrumentalized in the whole process in which it is already known that the human embryos will be used for therapeutic purposes and will be subject to patents after some procedures in which the stem cell in the human embryo is taken and subjected to a certain stage of this treatment would seem meaningful. When this point of view is accepted, developing a moral argument to meet the criticisms becomes striking.

On the other hand, considering the arguments for the ethical acceptability of HESCs, it becomes difficult to argue that patentability is a tool for instrumentalization. This will be the case especially for surplus human embryos or the human embryos with low result which are derived as a result of the application of assisted reproductive treatments. As stated above, within the framework of the principle that Harris named as the "Principle of Prevention of Waste", it is possible to say that the destruction of the human embryos that will already be destroyed for a good purpose such as treatment cannot be different from the organ transplantation from a patient with brain death. Here, the debate of whether instrumentalization by patenting would be possible will come to the fore, since it will not be possible to instrumentalize the human embryo with stem cell studies alone.

It will be better to emphasize once again that it would not be correct to consider the inventions to be made thanks to stem cells obtained by this method as if it is the same thing with the patenting of the human embryo. In our opinion, the human embryo is not suitable for patenting on its own. Its moral/legal status does not allow it. Just like organ donation, the human embryo should only be offered by donation, and it should be prohibited to sell it for financial gain. However, it is also clear that using surplus embryos for therapeutic purposes is a morally supportable way. For this reason, the use of surplus human embryos to find new treatment is morally acceptable, and should be encouraged and facilitated.

The fact that HESCRs are highly expensive should also be considered. The sustainability of these studies despite this cost depends only on the fact that some financial gains can be obtained thanks to the inventions that will emerge as a result of these studies. If this opportunity is not provided, these studies can be carried out in an extremely narrow and barren framework. By considering this point, it seems appropriate to provide the financial support required for the continuation of these researches and treatments, which serve a great purpose such as the benefit of

humanity, through patents. However, since the issue of patenting stem cell studies is an issue that directly affects human life in many ways, just like organ transplantation, every stage should be handled with sensitivity and all kinds of abuse should be prevented. For this reason, a condition of patentability will be that the works to be carried out are in accordance with public order and ethical principles. In addition, prescribing appropriate restrictions, will prevent violation and abuse of rights.

## 5. Conclusion

As it is seen, misunderstanding the term of human embryonic stem cell line and pretending as if it is the same thing with human embryo that has a potential to become a human being causes it to be understood as an unpatentable value. Likewise, interpreting the right to property in its traditional definition causes biotechnological inventions to have difficulties to succeed the criteria of patentability. However, developments in the medicine and science, the need for treatment for the severe human diseases, and the high costs of the human embryonic stem cell researches make the patent protection a necessity for the human embryonic stem cell lines. So, modern interpretations for fundamental rights and principles and new regulations on the biotechnological inventions become a need for such researches to be made and researchers to be supported for finding and developing treatments.

For a view in the doctrine, which we are agree with, providing the protection of the right to property to the human embryos is possible and it does not mean that human embryo is in the low status of a property. The sui generis legal status of the human embryo needs a sui generis protection. According to our point of view, providing the protection of both the personal rights of the donor and the right to property of the owner of the invention does not reduce the legal/moral status of the human embryo. On the contrary, providing extra protection is a proof for its high moral/legal status. Thanks to the obligations the personal rights impose its owner, the donors cannot have financial gain from selling their human embryos. And thanks to the obligations the personal rights impose to the third parties, the researchers cannot use the human embryos without their informed consent. Otherwise sanctions of private and criminal law appears because of the violation of personal rights based on the protection of the personal data of the donors and the research and it consequences become unpatentable. The same situation also appears with the right to property and accordingly patentability. Thanks to the prohibiton of having financial gain from the human body and its parts, a researcher cannot patent the human embryo or human embryonic stem cell. The researcher has to find a novel, inventive, and industrially applicable method for producing human embryonic stem cell lines or invent a new method for a treatment. The owner of the patent is restricted with both the criteria of patentability and the principle of human dignity. By this way owner of the patent right is supported for making expensive and difficult inventions for the human diseases to be treated and has to do it appropriately to the personal rights of the donor, criteria of patentability and the principle of human dignity.

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