

# Human Embryonic Stem Cell Patents: Friend or Foe for Moral Barriers?

María Ángela Bernardo-Álvarez  
Department of Public Law,  
Faculty of Law.  
University of León  
maberalv@gmail.com

## Las patentes de células madre embrionarias humanas: ¿Amigas o enemigas de las barreras morales?

**RESUMEN:** Las células madre embrionarias humanas son células pluripotentes con potenciales aplicaciones en medicina regenerativa e interés considerable en investigación y biotecnología. Sin embargo, dada la estrecha relación con principios morales y bioéticos, ha existido una considerable discusión sobre la posibilidad de patentar o no este tipo de células madre. En el presente artículo, se revisa la legislación europea en materia de propiedad industrial, y la tradición del sistema jurídico continental en el reconocimiento de la dignidad humana como principio fundamental y su relación con la protección de invenciones biotecnológicas, centrados en la reciente sentencia del caso *Brüstle v. Greenpeace e.V.*

**ABSTRACT:** Human embryonic stem cells (hESC) are pluripotent cells with recognised capabilities in regenerative medicine and a considerable interest in research and biotechnology. However, due to their close relation to bioethical and moral principles, there have been a considerable discussion about the possibility of patenting or not these hESC. Here, we report the European Patent Law and the tradition in the Continental legal system to recognise human dignity as its fundamental principle and their relation with the protection of biotechnological inventions, focused in the recent case *Brüstle v. Greenpeace e.V.*

**PALABRAS-CLAVE:** Propiedad industrial, biotecnología, células madre embrionarias humanas, patentes, bioderecho, dignidad humana, orden público, moralidad

**KEYWORDS:** Intellectual property, biotechnology, human embryonic stem cells, patents, biolaw, human dignity, public order, morality

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### 1. Introduction

On the 18<sup>th</sup> October 2011, the European Court of Justice disallowed patents involving human embryonic stem cells, commonly known as "hESC", (*Oliver Brüstle v Greenpeace e.V.* C-34/10 European Court of Justice, 2011). The ruling from the Court of Justice of the European Union claimed that processes and products that involve hESC must be forbidden, according to the interpretation of the *European Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions* (OJ 1998 L 213, 13).

Dr. Oliver Brüstle, the holder of the DE-197 56 864 patent, filed on 19 December 1997, is a German neuropathologist and a recognized expert in the field of stem cell research, and is currently working in the



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Institute of Reconstructive Neurobiology at the University of Bonn, Germany. In 1997, he filed a patent claiming the isolation and purification of neural precursor cells, obtained from hESC, in order to treat neurological disorders, such as Parkinson's disease.

In 2004, Greenpeace challenged that patent, arguing the protection of human life over economic interests and the defence of the non-commercialization of human embryos (Vogel, 2011). The patent was declared invalid by the Bundespatentgericht (*German Federal Patent Court Xa ZR 58/07*, 2009) and then referred to the Court of Justice of the European Union (Official Journal of European Communities C100/29, 2010), concerning the interpretation of "human embryo" and the patentability of "uses of human embryos for industrial and commercial purposes, including or not scientific research" (Harrison, 2011, 330-331).

Seven years later, the Court denoted a wide sense of the concept of "human embryo", not referred in a medical context, but restricted to the legal interpretation of the *European Directive 98/44/CE*, thus excluding any possibility of patentability where respect for human dignity could be affected. Besides that, this exclusion from patentability would cover the use of human embryos, not only for industrial and commercial use, but also for scientific research. However, the use of human embryos for therapeutic or diagnostic purposes which are applied to the human embryo and are useful to it is patentable.

The present study examines the interpretation of several ethical and legal declarations concerning the concept of human dignity; the impact and influence of the resolution of the case *Oliver Brüstle v Greenpeace e.V.* to the protection of biotechnological inventions is also revised.

## 2. The modern concept of human dignity

The modern concept of human dignity arises from the 18<sup>th</sup> century German philosopher Immanuel Kant, who defined it as a "universal attribute, an offshoot of the capacity for self-consciousness and practical reason, and the capacity for self-legislation and the control of the will by the categorical imperative belongs to all of us, and is the foundation of the right to respect and to treatment as an end rather than as a means" (Blackburn, 2005, 100). According to that definition, "the basis for human dignity is freedom for the will (or autonomy), which Kant understands as the ability to develop (or legislate) moral laws and follow those laws" (Resnik, 2007, 211-222).

After the World War II and the nazi Holoucast, a strong public opinion emerged in this context, claiming for a political declaration as a com-

mon standard of achievement for all peoples and all nations, recognising the inherent dignity and the equal and inalienable rights of human beings as the foundation of freedom, justice and peace in the world (*General Assembly of the United Nations, Resolution 217A (III)*, 1948). This declaration is known as the *Universal Declaration of Human Rights*, signed by the General Assembly of the United Nations in Paris in 1948.

Following this Declaration, the European Parliament, the Council and the Commission proclaimed the *Charter of Fundamental Rights of the European Union* (Official Journal of the European Communities C364/5, 2000), which recognises human dignity not only as a fundamental right *per se*, but as the basis of all the fundamental rights, introducing this concept into the European law.

Bearing in mind the *Universal Declaration of Human Rights* of 1948, the *Convention for the Protection of Human Rights and Fundamental Freedoms* of 1950 and the *Charter of Fundamental Rights of the European Union* of 2000, and considering the spectacular development of biology and medicine during the 20<sup>th</sup> century, several declarations were signed with the aim of, while considering the extraordinary benefits that science and technology could provide to the humanity, proclaiming the respect for human dignity, such as the *Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine*, commonly known as the *Convention on Human Rights and Biomedicine*, signed in Oviedo in 1997, (B.O.E. 251/20638, 1999, 36825-36830).

This Convention states the protection of human dignity and the primacy of the human being over the sole interest of society or science. Moreover, it proclaims the adequate protection of embryos, if law allows research on them. It also guarantees the prohibition of financial gain of any part of the human body or its parts. These statements are of relevant importance for the study of the protection of biotechnological innovations, focused on hESC patents.

Here it is very important to discuss the differences between United States and European Union's law. First of all, as it has been said before, the European Union proclaims human dignity as one of its more important values, with the signature or development of several relevant declarations. Thus, European law has a extraordinary specialty, the recognisment of the prohibition of making the human body a source of financial gain (Presidential Commission for the Study of Bioethical Issues, 2011), what results in a high level of human health protection.

However, the *United States Constitution* does not refer specifically to human dignity, which usually incorporates obligations of social solid-

riety, among with government support of positive welfare. Only one state (Montana) has incorporated in its own normative the human dignity clause, highlighting the nuclear importance of the US Supreme Court jurisprudence surrounding the constitutional values and principles. However, the history of international and foreign constitution-making and human rights declarations in the years following the end of World War II has an extraordinary importance in the Continental law, but not in the American case.

From a historical perspective, the differences in approach to develop a minimum core for the concept of human dignity also reflect the distinct national Courts' point of view to arrive at consensus. In the United States and also Canada, the US and Canadian Supreme Courts adopt a more individualistic approach (McCrudden, 2008, 655-724), while the European traditional law reflects a more communitarian view to understand the meaning of human dignity.

### 3. The concept of public order and morality

It is necessary to clarify the definition of public order and morality, as those concepts are reflected in the European law concerning the protection of biotechnological innovations.

Public order, with its threefold aspects of justice, peace and public morality, is the criterion that justifies the proper intervention of the state (Curran and McCornick, 1999). The term "public order" derives from the French legal concept of "*ordre public*", as it is not quite easily translated to English, is commonly used in the normative and it expresses concerns about matters threatening the social structures which tie a society together (UNCTAD/ICTSD Capacity Building Project on Intellectual Property Rights and Sustainable Development, 2002).

Laws that protect the *ordre public* are those that are so necessary for the good of the community that, when violated, the common good would be harmed. Such laws are indispensable to the society and include those affecting the exercise of authority (judicial power, administrative offices, parochial functions), governing meetings, public events and the public celebration of the liturgy, preventing offenses to the faith and laws given specifically for travelers. It is important to differ *ordre public* from uniformity of conduct, which may derivate in dictatorial polices (Beal, 2000, 66-67). It is significant that, beyond the English concept of "disturbance of the peace", a infringement of *ordre public*, from the point of view of the Continental law, would mean a violation of a basic constitutional right, thus, very related to the basical value of human dignity.

Morality, from the Latin *moralitas*, is restricted to the Kantian approach, based on notions, such as duty, obligations and principles of conduct, and what differs morality from ethics is the Aristotelian approach, based on a more practical reasoning and the concept of virtue (Blackburn, 2005, 241).

#### 4. Protecting innovation in Biotechnology: patent regulation

Patent law aims to promote technological innovation, and a patent may be defined as a “grant by the state of exclusive rights for a limited time in respect of a new and useful invention” (Grubb, 2000, 3).

According to the *Agreement on Trade-Related Aspects of Intellectual Property Rights - TRIPS* (World Trade Organization, 1994), the requirements for a patentable invention are novelty (in other words, the invention is not part of the state of the art, before the priority date of the invention), entailment of an inventive step (which is a critical point in biotechnological patents) and the capability of industrial application.

In the European Union, despite considerable efforts, a communitary patent has not yet been developed. However, in 1973, with the aim of unify the European Patent Law, the *European Patent Convention* (EPC) was created, which led in the establishment of the European Patent Office (EPO). Although the EPC set up a common patent grant system (in other words, the possibility of, by filling a single patent application, having a single examination by the EPO), it is important to take into account that patenting remains the responsibility of national patent offices.

Moreover, in order to promote innovation and to attract investment in Biotechnology, the European Union developed a specific Directive with the aim of establishing legal certainty about biotechnological inventions. This brought up the *European Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions* (OJ 1998 L 213, 13).

#### 5. Introducing moral barriers in biotechnological patent regulation

This *Biotech Directive*, together with the *EPC*, laid the foundations for the introduction of moral and ethical barriers in the European Patent Law, due to, as it has been said, the European legal tradition in the recognition of human dignity, *ordre public* and morality.

According to the article 6 of the *Biotech Directive* and the article 53(a) of the *EPC*, *ordre public* and morality are related to the ethical and

moral principles of each Member State, but pointing out the important of both principles in the field of biotechnology, as it is inherently connected to living matter, and with regard to it, exploitation and innovation protection shall not be deemed to be contrary to *ordre public* and morality, as it is prohibited by law.

On this basis, it is considered unpatentable: 1) Processes for cloning human beings; 2) processes for modifying the germ line genetic identity of human beings; 3) uses of human embryos for industrial or commercial purposes and 4) 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.

The first case where the EPO claimed a moral exclusion was the *case Relaxin*, (*Relaxin V8/94*, European Patent Office, 1995), where the Opposition Division established that only in rare and extreme cases for inventions which would universally be regarded as intolerable and offensive, *ordre public* and morality should be invoked. This case created the abhorrent-test, which established that patentability is precluded only if the general public finds the invention so abhorrent as to be inconceivable (Burhöi, 2006). Besides that, the reasoning in the decision of the case of the *Harvard oncomouse grant patent* (EPO Board of Appeal T0019/90, 1990) was made using the *ordre public* clause, as the production of these transgenic animals could not be reflected as negative from the *ordre public* and morality points of view, but as a possible benefit for the entire humanity (Martín Uranga, 2011).

## 6. Moral barriers in the stem cell patent regulation.

Nevertheless, it was not possible to invoke the *ordre public* and morality clauses in a case related to stem cell patents until the "*Edinburgh case*". This patent was granted for a procedure to "isolate embryonic stem cells from more differentiated cells in a cell culture in order to obtain pure stem cell cultures" (European Patent No. 0695351, 2002). The claims of the patent were not limited with the respect to the type of stem cells, which could lead to the production of stem cells from sources other than mice, in particular with human beings.

This patent was opposed by the governments of Italy, Germany and the Netherlands, and also by Greenpeace and the European Parliament for being contrary to the *ordre public* and morality clauses. During the discussion, it was pointed out that there were no uniform standards in Europe on hESC patents.

The final decision, was made possible in a wide sense, determining the acceptance of this patent, if the stem cells with human origins were excluded. That reason was argued not only because of the industrial and commercial purposes of human embryos, but also because the obtaining of this hESC meant the destruction of human embryos (Plomer, 2006). The ethical issue was the discussion of the principle regarding the non-commercialization of the human embryo and its production, and this ruling differentiates Europe from Japan and the United States (Knowles, 2009).

Later, following the rulings from the *Edinburgh case*, the Enlarged Board of Appeal of the European Patent Office rejected the *WARF patent application* (EPO Board of Appeal Decision G002/06, 2008), related to an invention made by Dr. James Thomson in 1996, who claimed a cell culture comprising human embryonic stem cells with a desired list of characteristics. At that time, such composition could only be made by a process that involved the destruction of human embryos. In the defence of this patent claims, the WARF argued that the EPO should consider the destruction of the embryos as a step preceding the invention rather than as one of the stages in the commercial exploitation of the invention (Sterckx and Cockbain, 2010).

As there were no moral standars for human embryonic stem cell patents, the EPO made a careful weighting of the moral objections and the invention's usefulness to mankind in order to adopt a decision. Using the article 53(a) of the *EPC*, the Enlarged Board of Appeal argued that the commercial exploitation of such human embryonic stem cells would be contrary to the *ordre public* and morality. Also, according to the Rule 28(c) of *EPC*, European patents shall not be granted in respect of biotechnological inventions (European Patent Office, 2007, 256-258), which in particular, concerns cases as the usage of human embryos for industrial or commercial purposes.

To summarise, in the European Union and the United States, several processes and products related to stem cells have been patented, such as processes for isolation of stem cells from embryos or tissues, processes for genetically modifying stem cells for particular applications, processes to create embryos by transferring a somatic cell nucleus to an enucleated egg for derivation of stem cells, processes to create non-viable "embryos" by parthenogenesis in order to provide autologous stem cells without the need of destroying viable embryos, and products such as stem cells, stem cell lines, differentiated stem cells or genetically modified stem cells. There have been over two thousand patent applications involving human and not-human stem cells, and approximately one third of all stem cell applications and one quarter of all embryonic

stem cell have been granted (European Group on Ethics in Science and New Technologies to the European Commission, 2002).

Although as it has been seen, various patent applications have been granted in the field of stem cells and embryonic stem cells, there have been some controversial cases, where several ethical principles raised involving this kind of patents, in one hand, the prohibition of making profits from the human body and its elements, and the principle of free and informed consent of the donor, and in the other hand, questions about the beginning of human life, the relative or absolute protection of human life in its different stages and the consideration of human dignity and moral status of the embryo.

### 7. Brüstle case: Has European patent law set the record straight?

It is obvious that problematic questions surrounding arguable scientific subjects, such as gene therapy or research with stem cells, fluctuate depending on the procedure used and the origin of the biological material needed (Villar Lacilla, 2011, 65-87).

In spite of the application of over two thousand stem cell patents, there was not a clear standard for the meaning of *ordre public* and morality, in relation to this type of patent grants. From the last years, scientists and taxpayers were asking for a explicit and obvious European policy in the guidance on how to grant or not a patent which could affect those moral and ethical questions. Apart from the controversial cases studied before, there was an urgent need to interpret clearly the article 6 of the *EPC* and how its understanding could affect the European stem cell patent granting.

Recently, the European Court of Justice, after the referring of the Bundespatentgericht (German Federal Patent Court) in the case *Brüstle v. Greenpeace e.V.*, interpreted the article 6(2)(c) of the *Biotech Directive*, not exempted of lots of controversy.

First of all, in its argument, the Court adopted an extremely wide meaning of the concept of human embryo, understanding it as 1) any human ovum after fertilisation; 2) any non-fertilised human ovum into which the cell nucleus from a mature human cell has been transplanted; 3) any non-fertilised human ovum whose division and further development have been stimulated by parthenogenesis.

Also, the European Court argued that it is for the referring Court, in this case the German Patent Court, to interpret, in the light of scientific developments, if a stem cell obtained from a human embryo at the blastocyst stage constitutes or not a human embryo.

This ruling, which means that no human embryonic stem cell patents should be granted if the generation of these hESC is based on the destruction of human embryos (similar to the *WARF case*), has opened up, at least in the academic and scientific field, Pandora's box. Before the sentence, there were some voices claiming for changes in the European patent regulation, as they were highlighting the inadequacy of European law for dealing with stem cell technology and applications (*Nature Neuroscience: Lagging laws*, 2010). Professors such as Dr. Pete Coffey, from the University College London (UCL), Dr. Ian Wilmut, from the Edinburgh University or Dr. Austin Smith, from the University of Cambridge, warned about the potential harm and risk to public health and patients' interests, if this translational research in stem cells could not be implemented through the European patent system (*New Legal Review: Stem of innovation snipped in European biotech ruling?*, 2011).

Although some authors, such as Gary Robin, CEO of the American biotech company ACT, think that this ruling will have a minimum effect on the usage of stem cells in medicine, as this technology would be granted in other regions, e.g. United States, it is important to appreciate that the European court argued that "an invention must be regarded as unpatentable, even if the claims of the patent do not concern the use of human embryos, where the implementation of the invention requires the destruction of human embryos", emphasizing that in the future, human embryonic stem cell patent could be granted if its generation was possible through an alternative to the destruction of human embryos, such as the single-blastomere method (*Business Wire: European Ruling May Not Impact Stem Cell Lines Derived Using Advanced Cell Technology's Single-Blastomere Method*, 2011).

Concerning about the problems that could arise from the patients' interests, lawyer Alexander Denoon stated that "under the current regulatory framework, it will be virtually impossible to convince a regulator to approve a generic, thus the regulatory protection for approved medicines will be very high" (*Genetics Policy Institute: CJEU Restricts the Patentability of Inventions Involving Embryonic Stem Cells*, 2011). So there should not be worries about stem cell therapies in Europe, they continue being a realistic hope in medicine.

Secondly, the European Court claimed that the exclusion from patentability concerning the usage of human embryo for industrial or commercial purposes covers also the purposes of scientific research. And finally, it was held that an invention is excluded from patentability where the implementation of the process requires, either the prior destruction of human embryos or their prior use as base material, even if, in the application, the description does not refer to the use of human embryos, as it occurs in the *Brüstle patent application*.

In conclusion, the European Court of Justice's Decision has followed the Advocate General's Opinion (*Oliver Brüstle v Greenpeace e.V.* C-34/10 *Advocate General's Opinion*, 2011), except from the point where the Court refers to the German Patent Court to claim if the stem cells obtained from a human embryo at the blastocyst stage constitute or not a human embryo, as the Advocate General claimed before. In his opinion, "embryonic stem cells, as are no longer capable of developing into a complete individual (pluripotent stem cells), they can no longer be categorized as human embryos".

## 8. Final considerations

During the last decade, many factors have contributed to generate a wide horizon of regulatory responses, in particular in a field (stem cell research and patent regulation), where the private conviction plays a very relevant role. From a human rights point of view, there will not be compromise of human dignity as the human embryo is not yet a bearer of human rights, because eggs are collected and embryos are derived from right-holders, always after understanding and signing their free and informed consent (Caulfield, Brownsword, 2006, 72-76). On the other hand, defenders of the traditional concept of human dignity understand that the destruction of human embryos to derive from them stem cells is a direct violation of human dignity.

The relation between moral and law, or in other words, the concerns about how general norms could be applied to particular cases, is particularly intriguing in the case of human embryonic stem cell patents. It is important to highlight the Precautionary Principle, due to the extraordinary development of science in the last decades, having a non-dogmatic perspective, from scientific, legal and ethical point of view. Law must not limit the remarkable advances that science could bring to humanity, but it should be kept in mind, that "*in dubio pro dignitas*" (Llamazares Fernández, 2011, 27-63). Having given that, the reasons why the Precautionary Principle is always interpreted in a negative sense are striking, because this situation does not take into account the right to benefit from advances in science and technology, with a considerable effect on global and public health.

In our opinion, the European Court of Justice's Decision about the *Brüstle v. Greenpeace e.V.* case pointed out the first steps to develop the standards of *ordre public* and morality related to biotechnological inventions' patents. It is necessary to take into account the tradition in the European law to understand the importance of the human dignity, *ordre public* and morality clauses as the possible exclusions while deciding if a patent should be or not granted.

However, in order to promote innovation in biotechnology and for its importance in medical applications, we consider that the definition of human embryo as it is stated in the Decision is too broad, as it is defined from a conservative perspective, not from a biological point of view. In our opinion, human embryo, according to the *Biotech Directive*, should be defined with respect to human dignity, but always bearing in mind its viability.

It is also intriguing why the Court does not adopt a decision about stem cells derived from a human embryo and let the German Patent Court to interpret this concept, moreover when many scientists understand that an isolated embryonic stem cell represents a cultural artifact and it can not be equivalent to cells of the embryo (Hansson *et al.*, 2007, 1507-1510). It seems that there is an ethical inconsistency, as hESC lines were generated during *In Vitro* Fertilisation (IVF) treatments, and the material used should not have morality *per se*, as it has not embryonic development potential.

In our opinion, human dignity, *ordre public* and morality clauses must be claimed only in extreme cases, where the hESC are derived from the destruction of human embryos, understanding them from a biological concept, thus it should only be defined as human embryos those with viability and potential to develop a human being.

Besides that, it will be necessary to provide a more comprehensive understanding of the European Patent Law, specifically in those questions about Biotechnology, in order to avoid generating a catastrophic public opinion surrounding critical point such as the public health or the patients' interests. It will be also necessary to establish that it will be impossible not to develop stem cell technologies in the 21<sup>st</sup> century, because the European Court of Justice's Decision will have a limited impact (similar to the effects that followed the WARF decision in 2008) on the development, protection and application of these treatments in medicine.

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