Anuario Mexicano de Derecho Internacional
ISSN: 1870-4654
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Universidad Nacional Autónoma de México
México

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The Juridical Conceptualization of the Human Embryo in the Law of the European Union. A Well-Aimed Step in the Wrong Direction
Anuario Mexicano de Derecho Internacional, vol. XIII, 2013, pp. 517-548
Universidad Nacional Autónoma de México
Distrito Federal, México

The Juridical Conceptualization of the Human Embryo in the Law of the European Union. A Well-Aimed Step in the Wrong Direction

La conceptualización jurídica del embrión humano en el derecho de la Unión Europea. Un paso bien intencionado en la dirección equivocada

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Artículo recibido el 21 de diciembre de 2011
Aprobado para publicación el 4 de septiembre de 2012

Anuario Mexicano de Derecho Internacional, vol. XIII, 2013, pp. 517-548,
México, D. F., ISSN 1870-4654

RESUMEN: Este trabajo realiza un análisis crítico de la concepción, por primera vez, del embrión humano en el Derecho de la Unión con la sentencia del Tribunal de Justicia de 18 de octubre de 2011, en el asunto C-34/10.Estas consideraciones son hechas para dar cuenta de la Decisión de la Oficina Europea de Patentes de 25 de noviembre de 2008, en el caso de WARF, los dictámenes del Grupo Europeo de Ética en Ciencia y Nuevas Tecnologías, así como de la jurisprudencia del Tribunal Europeo de Derechos Humanos.
Palabras clave: Derecho europeo de patentes biológicas, Concepto de embrión humano, Respeto del principio de la dignidad humana en los embriones, Bioética, Embriones somáticos.

ABSTRACT: This paper provides a critical analysis of the design, for the first time, of the human embryo in the EU law with the judgment of the Court of Justice of 18 October 2011 in Case C-34/10. These considerations are made to account for the decision of the European Patent Office on November 25, 2008, in the WARF case, the opinions of the European Group on Ethics in Science and New Technologies and the case-law of the European Court of Human rights.
Descriptors: Legal protection of biotechnological inventions in European Union Law, Concept of human embryo, Respect for the principle of human dignity in human embryos, Bioethics, Somatic Embryos.

RESUMÉ: Ce travail fait un analysis critique de la conceptualisation, par première fois, de l'embryon humain dans la Droit de l'Union avec le jugement de la Cour de Justice de 18 Octobre 2011, dans l'affaire C-34/10. Cettes considerations critiques sont faits par rapport la Decision du Bureau Européen des Patents de 25.11.2008, dans l'affaire *WARF*, les opinions du Groupe Européen d'Éthique dans les Sciences et les Nouvelles Technologies, ainsi comme par rapport la jurisprudence de la Cour Européenne des Droits de l'Homme.
Mots-clés: Droit Européen de patents biologiques, Embryon humain, Dignité humain des embryos humains, Bioéthic, L'embryon somatic.

I. Introduction: Biotechnological patents in a context of European Pluralism as regards the morals underlying the research on human embryos

As a matter of principle, Since its early start in the 70's, the research conducted on Human Embryos —originally in the context of IVF techniques— has been conditioned by the discussion on the ontological and ethical status of the Human Embryo. As far the former, it is possible to identify up to four feelings: a) Human Embryo being a person (actually, it is the first stage of any human being); b) Human Embryo being a thing (that is, a ball of cells lacking any specific qualification); c) Human Embryo being an intermediate reality, neither a person nor a thing; and finally, d) the so called "demiurgic position" facing the Human Embryo under which, we do not know what it exactly is.[1] Concerning the latter, it is also possible to find out three approaches to the moral value of the Human Embryo: a) it has the same moral value than a person; b) it lacks any moral value; and c) it is an object entitled to a specific legal protection which can be modulated on the basis of the way it has been created, the stage of its development and the purposes aimed at its use.[2]

The controversy around the research conducted on Human Embryos shows two opponents, following to SALLES. On the one hand there are those focusing their arguments on the potential harms and goods for human beings (including the own Human Embryos or born people suffering from serious maladies); on the other hand there are those stressing the social and cultural value of this field of research, independently of its eventual benefits for the society.[3]

A wide study in major academic works[4] leads us to conclude —coinciding with Professor ABEL I FABRE— that "indeed, there are very

[1] Bellver Capella, V., "Células madre, genes y clones: el sendero del posthumanismo", in Zurriaraín, R. G. (coord.), *Células madre, Ciencia, Ética y Derecho,* Madrid, Ediciones Internacionales Universitarias, 2009, p. 149.

[2] *Ibidem,* p. 150.

[3] Salles, A. L. F., "La clonación y el debate sobre células troncales", in Luna, F. and Salles, A. L. F. (coords.), *Bioética: nuevas reflexiones sobre debates clásicos,* Buenos Aires, Fondo de Cultura Económica, 2008, p. 338.

[4] See, at this point, Ollero, A., "El estatuto jurídico del embrión humano", in *Biotecnología*

few of these scientists, philosophers or theologians ready to interpret scientific data in a way allowing them to re-consider their own schemes of thought".[5] This author also concludes saying: "in this controversy around the research with Human Embryos we have so many convictions but so little dialogue".[6]

In this article we focus our attention on the discussion around the Human Embryo up to the 14th day after fertilisation. The dialectic surrounding this issue confronting two visions, that from a materialistic reductivism[7] and that defending the status of person for Human Embryos from the moment of conception,[8] would seem to us to have reached some kind of intermediate position, in the search of an universal and inclusive concept of person. This attempt would stress the idea of vulnerability and it could allow to consider a human person notwithstanding his/her evolutive stage and different health conditions.[9] This conciliatory approach is clearly evidenced in the judgment of 18th October, 2011 of the Court of Justice in the case c-34/10. Nevertheless, as we consider in this pages, the European Judge and the European Legislator have not wanted to handle a "hot potato", namely, the key question in this issue: how the European Law could (and indeed should) manage the

y posthumanismo, Ballesteros, J., and Fernández, E., (coords), Thomson Aranzadi, 2007, Cizur Menor, pp. 331 and ff.

[5] Abel i Fabre, F., *Bioética: orígenes, presente y futuro,* Madrid, Institut Borja and MAPFRE Foundation, 2007, p. 139.

[6] *Ibidem.*

[7] See, *inter alia*, Singer, P., *Ética Práctica,* Barcelona, Akal, 2009, pp. 161-162. Savulescu, J., *¿Decisiones peligrosas? Una bioética desafiante,* Madrid, Tecnos, 2012.

[8] See, *inter alia,* Bellver, V., "Razones para el rechazo de la clonación con fines de investigación biomédica", *Cuadernos de Bioética,* 2002, 1, pp. 75-86. Ballesteros, J., "Exigencias de dignidad humana en biojurídica", in *Manual de Bioética,* Barcelona, Ariel, 2001, pp. 351-374.

[9] Torralba Roselló, F., *¿Qué es la dignidad humana? Ensayo sobre Peter Singer, Hugo Tristam Engelhardt y John Harris*, Barcelona, Herder, 2005, p. 397. In opinion of this author, rather than defining a person on the basis of his/her external characteristics and habilities like the thought, we should focus on a definition which departs from its essential vulnerable condition, with a genesis, a development and an ending. Across this whole process, any person should be considered as such and consequently, he/she should be respected.

obvious diversity of positions currently existing in the European society regarding the beginning of human life?[10]

The patentability of inventions in Europe is ruled by different premises than those accepted in United States, being one of the main differences between both patent regimes that in Europe patent of biotechnological inventions are not allowed if it is estimated that it is in conflict with the public order or morality of one of the European countries.[11]

Actions brought for the annulment of the patent in Europe on the grounds of public order and morality is not new. The American *Biocyte Corporation* —latter integrated in *Avicord*— got the European patent EP 343.217 on blood cells from umbilical cords of the foetus and the new born child. Civil society groups in Europe challenged that patent because they considered it to be against moral and public order. On June 1999, the European Patent Office revoked its previous decision without any mention to public order consideration but it was justified as not including any "new invention". Some months later, the same European Patent Office granted the patent EP 0695351 to the University of Edinburgh and the Australian company *Stem Cell Sciences* to isolate, select and reproduce transgenic animal stem cells. On 24 July 2002 the patent was revoked due to a mistake: according to the application, the patent granted would include also human beings —as not having been specified non-human animals—. Again, it was a lot of pressure on the European Patent Office under moral and public order considerations which made it change its previous decision.

One could wonder then and later how persuasive moral and public order considerations can be to bring an action against a patent granted

[10] Soto Silva, R., "El derecho y la interpretación de los hechos biológicos: dos ejemplos de la actualidad (células madre y clonación), *Revista de Derecho (Valdivia),* vol. XIII, 2002, p. 75.

[11] See Opinion No. 16 of the *European Group of Ethics for Sciences and New Technologies to the European Commission* (from now on "The European Group of Ethics") on *The ethical aspects of patenting inventions involving human stem cells,* pp. 9 and 10. Available at *http://ec.europa.eu/bepa/european-group-ethics/publications/opinions/index_en.htm* (visited the 4th May 2012). The concept of public order (*ordre public*) implies the respect of human dignity which is in the root of human rights, as it is redacted in Article 1 of the Charter of Fundamental Rights of the European Union. The European Convention of Patents of 1973 (Munich Convention) makes a reference to the public order in Article 53 and the Directive 98/44 of 6 July 1998 also makes mentions to morality and public order in Article 6.

on human embryonic cells. This question seems to have found an answer in the judgment of 18 October 2011, in the Case C-34/10 *Oliver Brüstle v Greenpeace eV* where the Court of Justice, for the very first time, has provided the concepts of 'human embryo' and 'use for industrial or commercial purposes' in the European Union Law. In the following pages I will focus on the relevance of such conceptualisation in the Law of the European Union by identifying its *lights* (e.g. its innovative approach in comparison to previous Opinions from the European Group on Ethics and the case-law of the European Court of Human Rights) and its *shadows*.

II. The up-to-now authorized doctrine on the topic: the European Group on Ethics (EGE) Opinion No. 16 on the ethical aspects of patenting inventions involving human stem cells

Relying on Article 7 of Directive 98/44/EC,[12] 6 July 1998, *on the juridical protection of biotechnological inventions*, the European Group on Ethics redacted its Opinion No. 16, *on the ethical aspects of patenting inventions involving human stem cells* where it enounced some guidelines on the issue of patenting biotechnological inventions which latter were closely followed by the European Patent Office in its decision on the so called *WARF case*.[13] Concerning ethical aspects of patents involving human embryonic stem cells, the European Group on Ethics was concerned that the questions of the dignity and the moral status of the embryo remain indeed highly controversial in a pluralistic society as the European Union. Those who are opposed to human embryo research, cannot, *a fortiori*, consider any patenting in that field. Among those who consider research on embryos ethically acceptable, some may feel great reluctance towards patenting the resulting inventions, while others consider

[12] Official Journal L 213, 30/07/1998, pp. 13-21.

[13] Main Board of Appellation ("EBoA") of the European Patent Office decision of 25 November 2008 in the so called *WARF case*. See infra Section IV.1.

patenting inventions derived from embryo research as acceptable, especially given the potential medical benefits.[14]

In the European context of incertitude as regards the relevance of ethical consideration when patenting biotechnological invention implying Human Embryos, the European Group on Ethics did not expressly said it was ethically acceptable nor the contrary to patent such inventions.[15] It is interesting to note what the European Group on Ethics said as regarding cloning in the context of patents. It started by remembering that under Article 6.2 of Directive 98/44/EC, processes of cloning human beings are not patentable. According to the definition of cloning in paragraph 41 of the Preamble of this Directive, it seems open to question —and it was so confirmed by the European Group on Ethics— whether the ban on patents reaches only reproductive human cloning or it also includes the cloning of human stem cells for therapeutic purposes. The scientific procedure is similar in reproductive cloning and for therapeutical purposes but the opposition on the grounds of moral and public order in Europe is far different in both cases. The European Group on Ethics was cautious enough in this issue. It evoked its previous Opinion No. 15, of 14 November 2000, *On research with human stem cells* where it had already taken note of the strong ethical concern in Europe as regards the cloning of human stem cells. Consequently, in its Opinion No. 16, the European Group on Ethics recommended to prevent someone from patenting processes of creation of human embryos by way of cloning stem cells and at the same time emphasized the urgent necessity of opening a public discussion on this question.[16]

[14] *Opinion No. 16* of the *European Group of Ethics* on *The ethical aspects of patenting inventions involving human stem cells, op. cit.*, p. 13.

[15] Even inside the *European Group of Ethics* was impossible to reach a *consensus* on this topic when Opinion No. 16 *on the ethical aspects of patenting inventions involving human stem cells* was redacted. It was needed to include the dissident opinion of Professor Günter VIRT.: "Human embryonic stem cells are excluded from patentability because we cannot get embryonic stem cell lines without destroying an embryo and that means without use of embryos."

[16] *EGE*, Opinion No. 16, *op. cit.*, p. 17.

III. The revolutionary change introduced by the judgement of the Court of Justice of 18 October 2011 in the Case C-34/10 , Oliver Brüstle v Greenpeace eV

The facts in this case are the following: Mr Brüstle was the holder of a German patent which concerned isolated and purified neural precursor cells, processes for their production from embryonic stem cells and the use of neural precursor cells for the treatment of neural defects. It is claimed in the patent specification filed by Mr Brüstle that the transplantation of brain cells into the nervous system allows the treatment of numerous neurological diseases.[17] In order to remedy such neural defects, it is necessary to transplant immature precursor cells. This type of cell exists only during the brain's development phase, nevertheless the use of cerebral tissue from human embryos rises significant ethical questions and the previous ruling of the EBoA, 25 November 2008, in the WARF Case, made in practice very difficult for Mr Brüstle to be granted an European patent for such transplant of immature precursor cells. On the contrary, Mr Brüstle focused on the embryonic stem cells which offered him new prospects for the production of cells for transplantation. Thus, Mr Brüstle's invention made it possible, among other things, to resolve the technical problem of producing an almost unlimited quantity of isolated and purified precursor cells having neural or glial properties, obtained from embryonic stem cells.

Greenpeace eV brought an action for the annulment of the patent filed by Mr Brüstle in so far as certain claims under that patent concern precursor cells obtained from human embryonic stem cells. It considered that Mr Brüstle's invention was unpatentable under Article 2 of the Law on Patents, in the version in force on 28 February 2005. The Bundespatentgericht (Federal Patent Court) allowed in part the application made by Greenpeace and declared the patent filed by Mr Brüstle invalid in so far the first claim relating to precursor cells obtained from human embryonic stem cells and the twelfth and sixteenth claims re-

[17] In fact, the first clinical applications have already been developed, in particular for patients suffering from Parkinson's disease.

lating to processes for the production of precursor cells. Mr Brüstle appealed against that judgment at the referring court and that Court -considering that the outcome of the proceedings depended on the interpretation of certain provisions of Directive 98/44- asked the European Court of Justice the following questions:

1. What is meant by the term "human embryos" in Article 6(2)(c) of Directive 98/44 ...?

(a) Does it include all stages of the development of human life, beginning with the fertilisation of the ovum, or must further requirements, such as the attainment of a certain stage of development, be satisfied?

(b) Are the following organisms also included:

– unfertilised human ova into which a cell nucleus from a mature human cell has been transplanted;

– unfertilised human ova whose division and further development have been stimulated by parthenogenesis?

(c)Are stem cells obtained from human embryos at the blastocyst stage also included?

2. What is meant by the expression "uses of human embryos for industrial or commercial purposes"? Does it include any commercial exploitation within the meaning of Article 6(1) of [Directive 98/44], especially use for the purposes of scientific research?

3. Is technical teaching to be considered unpatentable pursuant to Article 6(2)(c) of the Directive even if the use of human embryos does not form part of the technical teaching claimed with the patent, but is a necessary precondition for the application of that teaching

(a) because the patent concerns a product whose production necessitates the prior destruction of human embryos,

(b) or because the patent concerns a process for which such a product is needed as base material?

This way, for the very first time, the Court of Justice of the European Union faced the concept "uses of human embryos for industrial or commercial purposes" within the meaning of Article 6(2)(c) of Directive 98/44. In the conclusions provided by the General Advocate —Mr. Yves BOT— on 11 March 2011, the view taken is that the concept of

a human embryo must have a Community understanding.[18] Contrary to the opinion of States that the definition of this concept had to be left solely to their discretion —as in fact has assumed the European Group on Ethics in its referred Opinion No. 16 and assumed by the European Court of Human Rights— the Court of Justice followed a surprisingly brief reasoning to conclude a Community understanding for the questions asked by the Bundesgerichtshof and thus ruled, as regards the first of those, that Article 6(2)(c) of Directive 98/44/EC of the European Parliament and of the Council of 6 July of 1998 on the legal protection of biotechnological inventions must be interpreted as meaning that:

- any human ovum after fertilisation,any non-fertilised human ovum into which the cell nucleus from a mature human cell has been transplanted, and any non-fertilised human ovum whose division and further development have been stimulated by parthenogenesis constitute a "human embryo";
- it is for the referring court to ascertain, in the light of scientific developments, whether a stem cell obtained from a human embryo at the blastocyst stage constitutes a "human embryo" within the meaning of Article 6(2) (c) of Directive 98/44.

As far as the second and third questions, the Court of Justice ruled that the exclusion from patentability concerning the use of human embryos for industrial or commercial purposes set out in Article 6(2)(c) of Directive 98/44 also covers the use of human embryos for purposes of scientific research, only for therapeutic or diagnostic purposes which are applied to the human embryo and are useful to it being patentable. Article 6(2)(c) of Directive 98/44 excludes an invention from patentability where the technical teaching which is the subject-matter of the patent application requires the prior destruction of human embryos or their use as basematerial, whatever the stage at which that takes place and even if the description of the technical teaching claimed does not refer to the use of human embryos.

[18] See the General Advocate's Opinion of 10 March 2011, in the case C-34/10, especially paragraph 61 on the grounds exposed in previous paragraphs 54 to 60.

Examining the reasoning followed by the Court of Justice one sees that before answering the three questions asked by the Bundesgerichtshof, the Court of Justice considered necessary to explain why such concept had to be defined autonomously and specifically for the Union Law.[19] In its opinion, this followed from the wording and the purpose of Directive 98/44, a harmonization directive,[20] and from the rules already developed by the Court in the initial case-law interpreting that legislation.[21]

Entering into the merits of the questions referred for a preliminary ruling, it is a fact that Directive 98/44 gives no definition of the concept of human embryo.[22] Similarly, its drafting history does not give any indication of the intended substance of the concept. Consequently, the General Advocate looked for elements which could serve as guidance for his task, namely the legislation of the Member States, the provisions of the directive and current scientific information.

Searching in the legislation of the Member States would be in vain for finding evidence of a unanimous conception. The provisions of Directive 98/44 provided an important indication: which follows from the wording and the approach taken by the directive leads us to define not life, but the human body. Consequently, it is the human body, at the various stages of its formation and development for which it demands protection when it declares it expressly unpatentable.[23] In other words, for the Court of Justice, as it also was for the General Advocate, the question to be asked would be what form, what stage of develop-

[19] Paragraphs 25 and 26 of the Judgment of 18 October 2011, in the Case C-34/10.

[20] Paragraphs 27 and 28 of the Judgment of 18 October 2011, in the Case C-34/10.

[21] Paragraph 29 of the Judgment of 18 October 2011, in the Case C-34/10. According to settled case-law, the need for uniform application of Union law and the principle of equality require that the terms of a provision of Union law which makes no express reference to the law of the Member States for the purpose of determining its meaning and scope must normally be given an autonomous and uniform interpretation throughout the Union. Clearly, Article 6(2)(c) of the Directive 98/44, which provides that uses of human embryos for industrial or commercial purposes are to be considered unpatentable, makes no express reference to the law of the Member States.

[22] Paragraph 31 of the Judgment of 18 October 2011, in the Case C-34/10.

[23] Paragraph 33 of the judgment of 18 October 2011, in the Case C-34/10. See also paragraph 77 of the Opinion of the General Advocate of 10 March 2011 in the case.

ment of the human body, should be given the legal categorisation of 'embryo'. For this aim, the Union legislature has stressed the principle whereby inventions must be excluded from patentability where their commercial exploitation offends *ordre public* or morality and points out that those two concepts correspond in particular to ethical or moral principles recognised in a Member State. Finally, in conjunction with the above considerations, current scientific information —and the inferences which can be drawn from its silences— cannot, at present, tell us when the human person truly begins[24]. In this ongoing process which commences with gamete fusion, is it possible to say this with indisputable scientific precision which is the only way to avoid ethical or moral questions. Put in this way, the question would then refer to a solution directly inspired by philosophical or religious considerations and would therefore seem impossible to formulate in a way which is acceptable to everyone.

In short, the General Advocate suggested —and he was followed by the Court of Justice— that it would be preferred to focus on the human body instead of considering the beginning of life. Consequently, the Court of Justice observed in paragraphs 34 to 37 of the judgment that Article 6(2)(c) of Directive 98/44 should be interpreted to the effect that the concept of a human embryo applies from the fertilisation stage to the initial totipotent cells and to the entire ensuing process of the development and formation of the human body.[25] In addition, unfertilised ova into which a cell nucleus from a mature human cell has been transplanted or whose division and further development have been stimulated by parthenogenesis are also included in the concept of a human embryo in so far as the use of such techniques would result in totipotent cells being obtained.[26]

[24] Paragraph 81 of the Opinion of the General Advocate of 10 March 2011, in the Case C-34/10.

[25] The next stage in the life of a human embryo occurs when the totipotent cells have given way to pluripotent cells (the blastocyst).

[26] The reason as observed by the General Advocate was that "whilst, in themselves, totipotent cells hold the capacity to develop a complete human body, the blastocyst is the product of this capacity for development at a certain moment. It is therefore one of the aspects of the development of the human body and constitutes one of the stages." See paragraphs 94 and 95 of the Opinion of the General Advocate in the Case C-34/10.

The Court of Justice seemed to think that it would be paradoxical to refuse legal categorisation as an embryo for the blastocyst, which is the product of the normal growth of the initial cells. This would essentially diminish the protection of the human body at a more advanced stage in its development. Any pluripotent cell in isolation could not therefore be regarded as constituting an embryo in itself. Taken individually, pluripotent embryonic stem cells are not included in the concept of Human Embryo because they do not in themselves have the capacity to develop into a human being. However, as Mr Brüstle explained in his observations to the Court, embryonic stem cells were obtained from the internal cellular mass of the blastocyst, which was then removed. In other words, it is an element of the human body, in the course of its development, which was therefore isolated in order to proliferate the cells contained in that cellular mass. According to the legal definition provided by the Court of Justice, an invention should be excluded from patentability, in accordance with Article 6(2)(c) of Directive 98/44/EC whenever the application of the technical process for which the patent is filed necessitates the prior destruction of human embryos or their use as base material, even if the description of that process does not contain any reference to the use of human embryos.[27] That was also the answer provided to the third question that the referring court asked the Court of Justice.[28]

As far as the second question referred for a preliminary ruling, the Court of Justice assumed the opinion that the General Advocate stated who had considered that making an industrial application of an invention using embryonic stem cells would amount to using human embryos as a simple base material. Such an invention would exploit the human body in the initial stages of its development.[29] Thus, the Court of Justice stated that the only exception to the prohibition of patentability would be the uses and inventions for therapeutic or diagnostic purposes which were applied to the human embryo and were useful to it.[30]

[27] Paragraphs 98 and 101 of the Opinion of the General Advocate of 10 March 2011, in the Case C-34/10.

[28] See paragraph 52 of the judgment of 18 October 2011, in the Case C-34/10.

[29] Read paragraphs 47 to 50 of the judgment of 18 October 2011 in the Case C-34/10, in comparison to paragraph 110 of the Opinion of the General Advocate in the same case.

[30] Paragraph 46 of the judgment of 18 October 2011, in the Case C-34/10.

IV. Relevance of the juridical conceptualisation of the Human Embryo in the European Union Law

1. *Unreasonably expanding the ratio decidendi of the European Patent Office (EBoA) Decision of 25 November 2008 in the WARF case*

Although the Directive on the legal protection of biotechnological inventions (98/44/EC) regulates patentability of biological material, including Human Embryonic Stem Cells, it is also true that there is no European Union consensus on the moral status of embryo and its products. Consequently, reflecting this wide diversity of moral cultures, there are different policies for patenting among national patent offices which may difficult to achieve a European patent consensus at this regards. The already referred *European Groups on Ethics'* Opinion No. 16 *On Ethical aspects involving the patenting of human stem cells* was a strong source of inspiration for the Main Board of Appellation ("EBoA") in the European Patent Office in its decision of 25 November 2008 in the so called *WARF case*.[31]

It was a ruling in an appeal connected to the so-called WARF/Thomson stem cell application describing a method for obtaining embryonic stem cell cultures from primates, including humans, and was filed by the Wisconsin Alumni Research Foundation (WARF) in 1995. In 2006, the Technical Board competent for the case referred it to the EBoA whose final decision was a refusal to grant a patent for an invention which necessarily involves the use and destruction of human embryos since it would be contrary to public order or morality in Europe, which was prohibited in the European Patent Convention and on the EU Biotechnology Directive (98/44/EC).

The decision of the Enlarged Board of Appellation of the European Patent Office was not a complete surprise. Certainly, it surprised many observers who could have expected a similar decision to that given in 1992 to the patentability of the "Harvard Oncomouse". Then, although

[31] Decision of the EboA (Use of embryos/WARF) of 25 November 2008, OJ EPO 2009, pp. 306 and ff.

a controversial issue was at stake, the European Patent Office agreed that a mouse produced through the injection and incorporation of an oncogene into the embryo with the purpose to provide for research into cancer was patentable.[32] The Decision was favourable because, as the European Patent Office stated:

> In the case at hand three different interests are involved and require balancing: there is a basic interest of mankind to remedy widespread and dangerous diseases; on the other hand the environment has to be protected against the uncontrolled dissemination of unwanted genes and moreover, cruelty to animals has to be avoided. The latter two aspects may well justify regarding an invention as immoral and therefore unacceptable unless the advantages, i. e., the benefit to mankind, outweighs the negative aspects.[33]

It was not a complete unexpected decision, however, because under the cover of Article 7 of the Directive 98/44/CE of 6 July, 1998 concerning the juridical protection of biotechnological inventions, the *European Group on Ethics* had redacted in 2002 the Opinion No. 16, *on the ethical aspects of patenting inventions involving human stem cells*[34]. In this sense, it is relevant to recall what the *European Group on Ethics'* stated in its Opinion No. 16:

> The Group is well aware that all procedures involving directly or indirectly the human embryo are controversial in the sense that they are based on presuppositions for instance concerning the beginning of human life and the question whether there should be an absolute or a relative protection of human life in its different stages. Political and legal decisions in these ethical matters may change the self understanding of what it means to be a human being in a given epoch and society.

[32] Decision of the European Patent Office No. 0 169762 (Onco.mouse/Harvard) 1992, OJ EPO 1992, pp. 588 and ff.

[33] *Ibidem*, p. 591.

[34] In this sense, the Wisconsin Alumni Research Foundation issued a statement on November 29, 2008, following the rejection of its stem cell patent claims before the European Patent Office: "… WARF emphasizes that this ruling by the EPO Enlarged Board of Appeal was based on European Union patent rules that are peculiar to Europe. There is no counterpart in United States patent law and therefore the EPO decision does not in any way affect WARF's patent rights in the United States…".

The question of the dignity and the moral status of the embryo remain indeed highly controversial in a pluralistic society as the European Union. Those who are opposed to human embryo research cannot, a fortiori, consider any patenting in that field. Among those who consider research on embryos ethically acceptable, some may feel great reluctance towards patenting the resulting inventions, while others consider patenting inventions derived from embryo research as acceptable, especially given their potential medical benefits…

There is at present a tendency to accept double morality where there is no coherence between different positions adopted by one country. For instance, one could expect that to consider research on human embryos to derive stem cells as unethical, might imply the prohibition of the import for research of embryonic stem cells derived from human embryos as well as of the use of potential therapeutically applications resulting from such research, which is not always the case[35] (Cursive is added).

We must not lose sight of the fact that the patent application No. 96903521.1[36] described a method by which primate embryonic stem cells derived from an embryo could be maintained *in vitro* for a long period of time without losing their potential to differentiate into any cell of the body. On 13 July 2004, an EPO examining Division refused to grant a patent for the application on the grounds that it was found to be not consistent with the European Patent Convention (EPC) essentially because the disclosed method of obtaining stem cells used as the starting material a primate (including human) embryo which was destroyed in the process. In late 2005, the Technical Board of Appeal competent in the case referred the case to the EPO's supreme judiciary body, the Enlarged Board of Appeal. The Enlarged Board of Appeal considered that under the European Patent Convention and the EU Biotechnological Directive 98/44/EC it is not possible to grant a patent for an invention which necessarily involves the use and destruction of human embryos. It must also be remembered that Article 53 —Exceptions to patentability— of the EPC as amended by the Act revision the European Patent Convention of 29 November 2000[37] says that European patents shall

[35] EGE Opinion No. 16 of 7 May, 2002, op. cit., paragraph 1.21, p. 13.

[36] Published as EP Nr. 0770125 under the title "Primate embryonic stem cells" filed by the Wisconsin Alumni Research Foundation, *WARF*, in 1995.

[37] See it in http://www.epo.org/law-practice/legal-texts/epc.html (visited the 4th May 2012).

not be granted in respect of: "(a) inventions the commercial exploitation of which would be contrary to 'ordre public' or morality; such exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States."

According to *WARF*, the opinion of the Enlarged Board of Appeal focused on the issue of the patentability of cells made using an embryo.[38] Nevertheless, it should be pointed out the peculiarity of the European Patent System —including moral considerations— which make it different to the United States Patent system where there is no reference to moral objections to patentability of inventions, as it was mentioned at the very beginning of these pages. The inevitable conclusion, therefore, was observed by the Enlarged Board of Appeal of the European Patent Office in the *WARF Case*,

> … Article 53 a) EPC excludes inventions from patentability if their commercial exploitation is against ordre public or morality… In this context, it is important to point out that it is not the fact of the patenting itself that is considered to be against ordre public or morality, but it is the performing of the invention, which includes a step (the use involving its destruction of a human embryo) that has to be considered to contravene those concepts.[39]

In a word, for the EBoA of the European Patent Office there was nothing else to discuss, since this was the legal frame for patents in Europe. By saying these words, the EboA was concerned that in some European countries is possible to get patents in cases involving the destruction of human embryos to obtain cells, because in the societies of these countries the patentability of such inventions and their commercial exploitation was not considered to be against the ordre public nor morality:

[38] "The Board made no determination of the patentability of claims based on any of the traditional criteria used to assess patentability: usefulness, novelty and non-obviousness. In fact, the opinion makes clear that its decision does not address the question of patentability in general of inventions relating to human stem cell cultures." See, the statement issued by Wisconsin Alumni Research Foundation on November 29, 2008, following the rejection of its stem cell patent claims before the European Patent Office.

[39] Point 29 of the EBoA Decision of 25 November 2008 in the WARF case.

> … the legislators (both the legislator of the Implementing Regulations of the EPC and of the Directive) wanted to exclude inventions such as the one underlying this referral from patentability and that in doing so; they have remained within the scope of Article 53 a) EPC and of the TRIPS Agreement. In view of this result, it is not necessary nor indeed appropriate to discuss further arguments and points of view put forward in these proceedings such as whether the standard of ordre public or morality should be a European one or not, *whether it matters if research in certain European countries involving the destruction of human embryos to obtain cells is permitted*, whether the benefits of the invention for humanity should be balanced against the prejudice to the embryo, or what the point in time is to assess ordre public or morality under Article 53 a) EPC. The legislators have decided, remaining within the ambit of Article 53 a) EPC, and there is no room for manoeuvre.[40] (Cursive is added)

According to the ratio decidendi of the *WARF* decision, researchers in those countries would keep on their research because, not at European but at least at national level and in the United States as well, they could get legal protection for their inventions. The main consequence of the judgment of the Court of Justice of 18 October 2011 in the case C-34/10 seems to be that from now on, not even at national level these researchers would get access to patent related to Human Embryos nor Human Embryonic cells when obtaining them the destruction of the Human Embryo is inevitable. The consequences for those researchers in next future are far from being blooming: stop researching in Europe, re start for some of them oversea.

2. *Unjustifically ignoring the Opinions of the EGE and the jurisprudence of the European Court of Human Rights*

What human dignity means remains a mystery in Europe due to the pluralism which characterizes its society. I has already referred to the up-to-now authorized doctrine on the topic: the European Group on Ethics (EGE) Opinion No. 16 *on the ethical aspects of patenting inventions involving*

[40] Point 31 of the EBoA Decision of 25 November 2008 in the WARF case.

human stem cells.[41] On its own, the European Court of Human Rights has dealt with eventual connotations of the principle of human dignity as regards the European Convention for the Protection of Human Rights and Fundamental Freedoms, of 11th November 1950,[42] adopting a very cautious approach to this issue. In fact, the pluralism of juridical orders is one of the main features of the European society and this fact is consistently recalled by the European Court of Human Rights when it has to interpret and implement dispositions of the European Convention on Human Rights or its Additional Protocols.

As far as the conception of the beginning of human life and its juridical implications, two sets of judgments seem to be of particular relevance. The first one, dealing with the nature and juridical condition of a human foetus is a judgment of the Grand Chamber of the European Court of Human Rights, of 8th July 2004 in the *case Vo versus France*. The second one deals with human embryos and is represented by judgments of 7th March 2006 (Chamber) and 10th April 2007 (Grand Chamber) of the European Court, both given in the *case Evans versus United Kingdom*.

The European Court of Human Rights, ruling as a Grand Chamber, said previously the same with different words in 2004 in the *case of VO v. France*[43]. Then, the European Court considered that the issue of when the right to life begins is a question to be decided at national level: firstly, because the issue has not been decided within the majority of the States which had ratified the Convention, in particular in France, where this question has been the subject of public debate; and, secondly, be-

[41] See *supra* epigraph II.

[42] ETS No. 5 as modified by Additional Protocol No. 14, in force since 1st June 2010, CETS No. 194.

[43] Judgment of 8 July, 2004. The case concerned an application brought by a French national, Mrs Thi-Nho Vo, who attended on 27 November 1991 the Lyons general Hospital for a medical examination scheduled during the six month of pregnancy. On the same day another woman, Mrs Thi Thanh Van Vo, was due to have a coil removed at the same hospital. Owing to a mix-up caused by the fact that both women shared the same surname, the doctor who examined the applicant pierced her amniotic sac, making a therapeutic abortion necessary. Having exhausted local remedies, Mrs Thi-Nho VO lodged an application before the European Court complaining of the authorities' refusal to classify the unintentional killing of her unborn child as involuntary homicide, relying on Article 2 of the European Convention on Human Rights.

cause there is no European consensus on the scientific and legal definition of the beginning of life. It also established that:

> At European level, there is no consensus on the nature and status of the embryo and/or foetus. At best, it can be regarded as common ground between States that the embryo/foetus belonged to the human race, its potential and capacity to become a person requires protection in the name of human dignity, without making it a person with the right to life for the purpose of Article 2.[44]

The same conclusion was achieved two years later in the *case Evans v. United Kingdom,* judgments of 7 March, 2006 (Chamber) and of 10 April, 2007 (Grand Chamber).[45] In both judgments the European Court of Human Rights refused to recognise eventually the right to life under Article 2 of the European Convention of Human Rights to human embryos. Furthermore, this Court even self-restrained of willing to judge at European level on the question concerning the beginning of human life, considering the wide margin of appreciation any European country has been given on the matter.

As far as the facts of the case, on 10 October 2000 the applicant and J were informed, during an appointment at the clinic that preliminary tests had revealed that the applicant had serious pre-cancerous tumors in both ovaries, and that her ovaries would have to be removed. They were told that because the tumors were growing slowly, it would be possible first to extract some eggs for *in vitro* fertilization ("IVF"). On 12 November 2001 the couple attended the clinic and eleven eggs were harvested and fertilized. Six embryos were created and consigned to storage. On 26 November the applicant underwent an operation to remove her ovaries. She was told that she should wait two years before attempting to implant any of the embryos in her uterus. In May 2002 the relationship broke up. The future of the embryos was discussed between the parties. On 4 July 2002 J wrote to the clinic to notify it of the

[44] Paragraphs 82 and ff. of the Judgment. The European Court of Human Rights also remembered that not even the Convention on Human Rights and Biomedicine of 1997 (Oviedo Convention) nor its Additional Protocol of 2005 concerning Biomedical Research include a definition of human being or of a person.

[45] See paragraphs 45 to 47 in the former and paragraphs 54 to 56 in the latter.

separation and to state that the stock of embryos should be destroyed. Since that moment, a legal battle started between both parts reaching the European Court of Human Right's judgment of 7 March 2006.

Before the European Court the applicant claimed that the relevant provisions of the 1990 Human Fertilization and Embryology Act, which required her former partner's consent before the embryos made with their joint genetic material can be implanted in her uterus, violate her rights under Articles 8 and 14 of the Convention, and the embryos' right to life under Article 2.

Concerning the alleged violation of Article 2 of the European Convention, the Court recalled in paragraph 46 of his judgment what has already observed in *Vo v. France,*[46] that, in the absence of any European consensus on the scientific and legal definition on the beginning of life, the issue of when the right to life begins comes within the margin of appreciation which the Court generally considers that States should enjoy in this sphere. Under English law an embryo does not have independent rights or interests and cannot claim —or have claimed on its behalf— a right to life under Article 2. Consequently, there had not been a violation of that provision in the present case.[47] As far the rest of her allegation relating Articles 8 and 14, the European Court's assessment was the following to finally reach the conclusion that it had not been violation of Article 8 (held by five votes against two) nor of Article 14 (held unanimously).

The Court observed at the outset that since "private life" is a broad term, it incorporates the right to respect for both the decisions to be-

[46] Grand Chamber, no. 53924/00, § 82, ECHR 2004. The European Court had considered that the issue of when the right to life begins is a question to be decided at national level: firstly, because the issue has not been decided within the majority of the States which had ratified the Convention, in particular in France, where this question has been the subject of public debate; and, secondly, because there is no European consensus on the scientific and legal definition of the beginning of life. It asserted that "At European level, there is no consensus on the nature and status of the embryo and/or foetus. At best, it can be regarded as common ground between States that the embryo/foetus belonged to the human race, its potential and capacity to become a person requires protection in the name of human dignity, without making it a person with the right to life for the purpose of Article 2."

[47] Paragraph 47 of the judgment of 7 March 2006.

come and not to become a parent.[48] The 1990 Act prevented the clinic from treating the applicant once J had withdrawn his consent. Thus, for the European Court, the question which arises is whether there exists a positive obligation on the State to ensure that a woman who has embarked on treatment for the specific purpose of giving birth to a genetically related child should be permitted to proceed with the implantation of the embryo notwithstanding the withdrawal of consent by her former partner, the male gamete provider.[49] To give an answer, the European Court firstly, observed that there is no international consensus with regard to the regulation of IVF treatment or to the use of embryos created by such treatment.[50] Thus, even though the great sympathy for the plight of the applicant who, if implantation did not take place, would be deprived of the ability to give birth to her own child, the European Court did not consider contrary to Article 8 the 1990 Act which did not have a power to national authorities to override a genetic parent's withdrawal of consent.

The jurisprudence of the European Court of Human Rights which have contributed to confirm the European pluralism regarding the beginning of human life and the concept of human being defended by the European Group of Ethics seems to have been over passed in an unjustifiable way by the Court of Justice in its judgment of 18 October 2011. It should be mentioned in passing that even the Enlarged Board of Appeal of the European Patent Office (EBoA) —having to pronounce itself on the meaning of human embryo in the so called WARF case—, concluded that what is an embryo is a question of fact in the context of any particular patent application.[51] In a similar approach, the General

[48] Paragraph 57 of the judgment of 7 March 2006.

[49] Paragraph 58 of the judgment of 7 March 2006.

[50] Paragraphs 61 and 62 of the judgment. In this context declared the European Court that: "Since the use of IVF treatment gives rise to sensitive moral and ethical issues against a background of fast-moving medical and scientific developments, and since the questions raised by the case touch on areas where there is no clear common ground amongst the Member States, the Court considers that the margin of appreciation to be afforded to the respondent State must be a wide one".

[51] Points 19 and 20 of the EBoA Decision of 25 November 2008 in the WARF case: "The European Union and the EPC legislators must presumably have been aware of the definitions used in national laws on regulating embryos, and yet chose to leave the term undefined. Given

Advocate in his Opinion in the preliminary ruling in the Case C-34/10 adopted a cautious position when he observed that :

> … It also worth pointing out that the legal definition which I will propose falls within the framework of the technical directive under examination and that, in my view, legal inferences cannot also be drawn for other areas which relate to human life, but which are on an entirely different level and fall outside the scope of Union law. For that reason, I consider that the reference made at the hearing to judgments delivered by the European Court of Human Rights on the subject of abortion is, by definition, outside the scope of our subject. It is not possible to compare the question of the possible use of human embryos for industrial or commercial purposes with national laws which seek to provide solutions to individual difficult situations.[52]

This is also the intention of the Court of Justice when it stated that:

> As regards the meaning to be given to the concept of 'human embryo' set out in Article 6(2)(c) of the Directive, it should be pointed out that, although, the definition of human embryo is a very sensitive social issue in many Member States, marked by their multiple traditions and value systems, the Court is not called upon, by the present order for reference, to broach questions of a medical or ethical nature, but must restrict itself to a legal interpretation of the relevant provisions of the Directive.[53]

I think that both, the General Advocate and the Court of Justice are terribly wrong when they consider that it will be enough for resolving such a controverted issue like human dignity is, to distinguish between a commercial and a private use of human embryos, taking for granted

the purpose to protect human dignity and prevent the commercialisation of embryos, the Enlarged Board can only presume that 'embryo' was not to be given any restrictive meaning in Rule 28, formerly 23 d) EPC, as to do so would undermine the intention of the legislator, and that *what is an embryo is a question of fact in the context of any particular patent application.*" (Cursive is added)

[52] Paragraph 49 of the Opinion of the General Advocate of 10 March 2011 in the Case C-34/10.

[53] Paragraph 30 of the judgment of 18 October 2011 in the Case C-34/10.

that in the former case is possible an European approach whereas in the latter is preferable a national and particularised position. In both cases there are questions of moral and public order for which European Union Law hardly can provide solution without a political will of legislators at national and supranational level. In this sense, I find particularly relevant the statement of the General Advocate when says in paragraph 90 in fine of his Opinion:

> … Directive 98/44 does state that a practice is not contrary to *ordre public* merely because it is prohibited by the Member State. The assessment with regard to *ordre public* must be made having regard to the rules laid down in the directive. What is authorised by the directive could no longer be prohibited by national law.

Thus, the main consequence of this *démarche* of the Court of Justice in the case C-34/10 is that the conceptualisation of human embryo in the European Union Law implies to put a limit to the margin of discretion held up to now by Member States as to individually manage moral and public order considerations to grant biotechnological patents at national level and also to opposite they being granted at European level. In my opinion, the judicial conceptualization of the Human Embryo in the Law of the European Union can be described as a well-aimed step in the wrong direction. It is a judgment inconsistent with the current situation of European countries showing an effective normative divergence in the field of Human Embryonic research. A true European convergence in matter of embryonic research, at least at level of informing principles, seems a previous condition *sine qua non* for a harmonisation in Europe as regards biotechnological patents implying Human Embryos[54]. The inexistence of such informing principles could be interpreted as an expression of the European legislator's desire of respecting the margin of appreciation of European Members to regulate research in this field at their will, considering the moral and public order considerations of their own societies. Is this interpretation correct, hardly would a real European harmonization on patents could be reached to protect the results of such researching only by way of the Court of Justice judgment of 18 October 2011.

[54] The General Advocate recognized in paragraph 44 of his opinion the close relation between research and patent regimes.

V. Questions unresolved with the new démarche: embryos derived from cellular reprogramming techniques with somatic nuclear transfer (somatic embryos)

As a matter of fact, it is true that the aim of activating ovocite with nuclear transfer of adult somatic reprogrammed cells is not to create human embryos but an embryonic body, something different.[55] This is so understood by most of authors[56] but not unanimously.[57] However, Science keeps advancing at present rate making possible to create human pre-embryos and embryos with the technique of nuclear transfer of adult reprogrammed cells which would be *totipotent* and not only *pluripotent*. For example, Induced Pluripotent Stem Cells (iPSCs) can be injected by micropipette into a trophoblast and the blastocyst being transferred to recipient females. Chimerical living mouse pups could be created: mice with iPSCs derivatives incorporated all across their bodies with 10%-90% chimeras. Consequently, a dilemma would rise in countries like United Kingdom and Spain.[58] We consider here the general sense of totipotency, as the General Advocate did in his opinion in the Case C-34/10, like the ability of a single cell to generate an en-

[55] Human Embryonic stem cells naturally reside within the inner cell mass (embryo blast) of blastocyst, and in the embryo blast, they differentiate into the embryo while the blastocyst's shell (trophoblast) differentiates into extra embryonic tissues. The hollow trophoblast is unable to form a living embryo and thus it is necessary for the embryonic stem cells within the embryo blast to differentiate and form the embryo.

[56] See, for instance, López Moratalla, N., "Clonación terapéutica", *Persona y Bioética,* Vol. 8, No. 22, 2004.

[57] See as this regards, Znidarsic, V., "Biomedical research in Andalusia: a critical approach from Slovenia", in *Régimen Jurídico de la investigación biomédica en Andalucía (Daniel García San José coord.)* Ed. Laborum, 2009, pp. 205-206.

[58] The Autonomous Community of Andalusia has competence under Spanish Constitution and its *Statute* to develop research on human cells. See Andalusian Act 1/2007, of 16 March 2007, of researching in cellular reprogramming exclusively for therapeutic purposes in Andalusia, BOE No. 89, 13 April 2007, pp. 16299 to 16302 (it can be consulted into English in http://www.grupo.us.es/biodeinter). At national level, Biomedical research is regulated in Spanish Act 14/2007, 3 July 2007, of biomedical research in Spain, BOE No. 159, 4 July 2007 (it can be consulted into English in http://www.catedraderechoygenomahumano.es/int_normativa.asp (visited the 4th May 2012)

tire individual.[59] In such case, Autonomic commissions and committees with competence in this field, namely the Committee of Researching in Cellular Reprogramming could make a literal interpretation of Act 1/2007 and consider that nuclear transfer of adult somatic reprogrammed cells are authorised even in case of human pre-embryo (still called somatic pre-embryo) is created exclusively for therapeutic purpose. That is, not just to germinate specific lines of stem cells but any human body cell and thus, ready to derive in chimerical embryos, as it successfully happened in China in 2009 with chimerical mice. As it was worldwide commented,[60] Chinese scientists published in the summer of 2009 two works in the journals *Nature*[61] and *Cell Stem Cell*[62] where they asserted to have created live mice from mature skin cells that had reverted to an embryonic-like state. There is little doubt that such scientific success could overlap controversy surrounding somatic embryonic stem cells putting at the same ground than Human Embryonic stem cells as not being object of patent in Europe.

VI. Foreseeable consequences of the juridical conceptualisation of Human Embryo in the European Union Law

The Court of Justice of the European Union had affirmed in past that the fundamental right to human dignity was part of the European Union

[59] See Testa, G., Borghese, L., Steinbeck, J. A. and Brüstle, O., "Breakdown of the Potentiality Principle and Its Impact on Global Stem Cell Research", *Cell Stem Cell* 1, 2007, pp. 153-156.

[60] See, i.e. *The Washington Post*, July 24, 2009.

[61] The work of the team of scientists led by Qi Zhou of *the Chinese Academy of Sciences* was published in *Nature* vol. 460, No. 7254, July 23, 2009: 37 iPS cell lines created, three of which produced 27 live offspring, the first of which they named Tiny. One of the offspring, a 7-week-old male, went on to impregnate a female and produced young of its own.

[62] The work of the team of researchers led by Shaorong GAO of *the National Institute of Biological Sciences in Beijing* appeared published in *Cell Stem Cell*, Vol. 5, Issue 2, 135-138, 23 July 2009: five iPS cell lines, one of which was able to produce embryos that survived until birth. Four animals were born but only one lived to adulthood.

Law and as a legitimate interest which must be protected by the European Union itself and by its member States even if such protection is in contradiction with European Law dispositions.[63] Thus, it seems of particular relevance the paragraph No. 96 of the General Advocate's Opinion where he said that "… Human dignity is a principle which must be applied not only to an existing human person, to a child who has been born, but also to the human body from the first stage in its development, i.e. from fertilisation".

In my opinion such statement, not reproduced in the judgment of the Court of Justice of 18 October 2011 but inferring the whole reasoning followed by it, does not seem to be the best way to put an end to a discussion opened for the latest years in Europe. In effect, the unique Interpretative Declaration added to States signatures of the Additional Protocol to the Convention on Human Rights and Biomedicine on the Prohibition of Cloning Human Beings (ETS No. 168) was that of The Netherlands. It concerned the words "dignity of human beings" in Article 1 of the Convention on Human Rights and Biomedicine (ETS No. 164), as referred in last paragraph of the Preamble of this Additional Protocol.[64] In opinion of this country, the words "human dignity" in both texts, Convention and Protocol, were only referring to the dignity of any human being; that is, the dignity of a born person. The purpose of this interpretative declaration was evident: to let clear that The Netherlands stayed apart from other countries, like the Holy See,[65] which invoked human dignity of the human being in a wide sense, like a species and thus including human embryos.

[63] Case C-377/98, *Netherlands v. European Parliament and Council* (2001) ECR I-7079, paragraphs 70 and ff.. Case C-36/02, *Omega Spielhallen und Automatenaufstellungs GmbH v. Obergurgermeiterin der Bundesstadt Bonn* (2004) ECR I-9609, paragraphs 30 to 35. Case C-456/03, *Commission v. Italy* (2005) ECR I-5335.

[64] In the Preamble of the Additional Protocol one can read "Considering the purpose of the Convention on Human Rights and Biomedicine, in particular the principle mentioned in Article 1 aiming to protect the dignity and identity of all human beings." Article 1 of the Convention on Human Rights and Biomedicine states: "Parties to this Convention shall protect the dignity and identity of all human beings and guarantee everyone, without discrimination, respect for their integrity and other rights and fundamental freedoms with regard to the applications of biology and medicine".

[65] See "Clonage et recherche embryonnaire", *La documentation catholique,* No. 2261, 2002.

Such Interpretative Declaration by The Netherlands hardly would be compatible with the sense given to "human beings" in the Convention on Human Rights and Biomedicine where it is combined —without confusion— "person" (any particular and individual human being) and the "human beings", as including the human life in all its forms, embryonic and already born. Thus, the word "person" is used here with a similar meaning as it is employed in the European Convention for the Protection of the Human Rights and Fundamental Freedoms, of 11th November, 1950. That is, as referring to those who are subject of Law, with rights and duties? The words "human beings", on the contrary, is used in the Convention on Human Rights and Biomedicine meaning human life in all its forms to bring protection to human dignity and identity since the very moment of conception. Consequently, Article 13 of the Convention on Human Rights and Biomedicine, on interventions on the human genome gains a practical meaning. Nevertheless, it was let as an open question the meaning of human dignity in the *Explanatory Report to the Additional Protocol to the Convention on Human Rights and Biomedicine on the Prohibition of Cloning Human Beings* which recognised in point 6: "In conformity with the approach followed in the preparation of the Convention on Human Rights and Biomedicine, it was decided to leave it to domestic law to define the scope of the expression 'human being' for the purposes of the application of the present Protocol".

Furthermore, it may be interesting to recall that in the *Charter of Fundamental Rights of the European Union*, in Chapter I (Dignity) it is made a reference to human rights facing cloning in Article 3 (right to physical integrity)[66] and not in Article 2 (right to life).[67] Thus, it could seem

The Holy See took part in the drafting of this Additional Protocol although it finally did not sign it.

[66] Article 3. 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 of making the human body and its parts as such a source of financial gain- the prohibition of the reproductive cloning of human beings."

[67] Article 2. Right to life: "1. Everyone has the right to life. 2. No one shall be condemned to the death penalty or executed". Note that it is immediately after Article 1. Human dignity: "Human dignity is inviolable. It must be respected and protected".

argued that for the drafters of this legally binding iinternational instrument in Europe after the Lisbon Treaty, that dignity refers to a person, namely, any born person and not to the human being, like specie, in the widest sense of any human life whatever conception one might have of it. The judgment of the Court of Justice of 18 October 2011 implies that the protection of human dignity cover not only that of the born person but also that of the unborn person, that is, in stage of Human Embryo. Member States have to accept what probably they could describe as an unreasonable excersise of judicial activism. Nevertheless, it will still be room for controversy because the Court of Justice and the General Advocate have not specified the grounds for the protection of the dignity of the Human Embryo, that is, like a consequence of its moral status or of its moral value, two different things. Authors like Bonnie STEINBOCK, prefer to assert that very early, extra corporeal embryos do not have moral status but moral value, consequently, any human embryo is to be respected and cannot be treated as 'stuff' of no moral significance.[68] The distinction this author proposes between moral status and moral value concerns the kind of reasons invoked for such respect: whereas in the moral status, protection for respect stems from their interest or welfare, in the moral value this is not possible because human embryos are non sentient beings (like works of arts, ancient oaks, wilderness areas and so on). The inevitable conclusion, therefore, is that due respect to human embryos as a form of human life is secured using them only for morally significant purposes, such as enabling infertile people to become parents and in research that could cure devastating diseases or save lives.[69]

[68] Steinbock, B., "Moral Status, Moral Value and Moral Embryos: Implications for Stem Cell Research", in Steinbock, Bonnie (ed.), *The Oxford Handbook of Bioethics,* Oxford University Press, 2007, p. 433.

[69] *Ibidem,* p. 438. In this example, author argues that medical research having the potential to prolong and improve people's lives is at least as valuable as enabling infertile people to become parents, in order to which many of embryos that are created are not used to establish a pregnancy, but are frozen and ultimately discarded. Nothing to object the justification for the creation of excess embryos is to spare the woman several rounds of superovulatory drugs, which is both physically burdensome and expensive. Nevertheless, let's apply for the similar treatment in medical research.

VII. Concluding remarks

It is particularly true in the field of Biotechnology that Science moves faster than Law, always lagging behind the facts.[70] In Europe it does not exist at present a common conception of the beginning of human life, let alone as regards the margin of discretion Sates should have in regulating the research with Human Embryos and to protect with patents the results of such research. The decision on appeal of the European Patent Office in the so called *WARF Case*, of 25 November 2008, is expression of the principle of the gradual conception of the human life protection and of the prohibition in Europe of destroying human embryos to get human embryonic stem cells. In its proper measure, the EPO decision showed that it is not allowed to patent at European level the process of creation of a human embryo specifically to the purposes of experimentation and research. Although this may be allowed in United States with private founds, or in some European countries which are not bounded by Article 18 of the European Convention on Human Rights and Biomedicine (Oviedo Convention), such a research implying the creation-destruction of human embryos finds out a solid opposition in part of the European Society under moral grounds. Consequently, the patentability at European level of this kind of inventions would not be possible under Article 6 of the European Directive on patentability of biotechnological inventions and considering Article 53 a) of the EPC, as it was remarked by the *European Group on Ethics* in its Opinion No. 16 of 7 May, 2002 on the Ethical Aspects of Patenting Inventions involving Human Stem Cells.

The situation of variable geometry in Europe as regards regulation of researching in human embryonic stem cells is a reality[71] with unknown

[70] See in this sense the crucial statement made by the General Advocate in paragraph 48 of his Opinion of 11 March 2011 in the Case C-34/10: "Consequently, in my view, the solution which I propose or the solution adopted by the Court will apply only at the time it is established. Advances in knowledge may lead to it being modified in future."

[71] *EGE, Recommendations on the ethical review of hESC FP7 research projects,* Opinion Nº 22, 2007, p. 32. Available at *http://ec.europa.eu/bepa/european-group-ethics/publications/opinions/index_en.htm* (visited the 4th May 2012).

consequences. As already said, the main ground for criticising the judgment of the Court of Justice in its judgment of 18 October 2011 is two folds: on the one hand, it unreasonably expands the *ratio decidendi* of the European Patent Office (EBoA) Decision of 25 November 2008 in the *WARF case* and the consequence is that not even at national level patents related to Human Embryonic stem cells will be allow for being contrary to the European Union Law. On the other hand, it unjustifiably ignores the Opinions of the EGE and the jurisprudence of the European Court of Human Rights which have been fully respectful with the expressed will of European countries to be let a margin of appreciation at this regard. The conceptualisation of the Human Embryo in the European Union Law puts an end to the margin of discretion traditionally held by Member States for considering moral and public order constraints at national level to opposite the granting of biotechnological patents at European level. Nevertheless, this new *démarche* would have, nevertheless, very little consequences into the current situation of European patents if it is not followed by an effective normative convergence in the Human Embryonic research at European level, at least, at level of informing principles.

These informing principles would seem necessary for a true European convergence in matter of embryonic research as a previous condition for a harmonisation in Europe as regards biotechnological patents implying Human Embryos.

Considering the particular situation of European countries like United Kingdom or Spain, although researching with induced pluripotent stem cells seems to overlap moral objections to nuclear transfer techniques which imply destroying early-stage embryos, the key stone of the matter is the lack of a European common conception of human life and concerning the beginning of human life. It is reasonable to think that there is a risk that the distinction between somatic and human embryos, depending on cellular reprogramming or human cloning techniques, will be weaker and weaker in future. The works of two Chinese scientist teams published in 2009 in *Nature* and in *Cell Stem Cell* noticing to have created live mice from mature skin cells that they had reverted to an embryonic-like state, should be seen as an evidence of such a risk. Furthermore, even though what it is at stake is a somatic embryo and

not properly a human embryo, Science makes possible cellular reprogramming techniques without being necessary the method of somatic nuclear transfer, as it is applied in Spain. Consequently, situation in near future might be particularly worrying in the case of trying to patent the inventions resulting from research currently developed, considering the binding guidelines provided by the judgment of 18 October 2011 of the Court of Justice and the ruling of the Enlarged Board of Appeal of the European Patent Office in the so called *WARF case* concerning patentability of biotechnological inventions implying the use of human embryos. That is, refusing to grant European patents protection for any controverted technique considered contrary to public morals and human dignity of the European society were to be proved the existence of less morally controverted techniques. As a matter of fact, these techniques already do exist. In *Science Daily*[72] it could be read in its edition of 12 February 2008: "University of California —Los Angeles Stem Cell Scientists has reprogrammed human skin cells into cells with the same unlimited properties as embryonic stem cells without using embryos or eggs—.[73] Further works published in 2009 confirmed this point.[74] The situation we envisage in the near future is particularly worrying in the case of the research at present being done in Europe, even more considering planned research for next years.

[72] *http://www.sciencedaily.com/releases/2008/02/080211172631.htm.*

[73] As it could be read in this piece of news, the UCLA study confirmed the work first reported in late November 2008 of researcher ShinyaYamanaka at Kyoto University and James Thomson at the University of Wisconsin. Taken together, the three studies demonstrated that human iPS cells could be easily created by different laboratories and were likely to mark a milestone in stem cell-based regenerative medicine: "*Besides these new techniques to develop stem cells could potentially replace a controversial method used to reprogram cells, somatic cell nuclear transfer (SCNT), sometimes referred to as therapeutic cloning.*"(Cursive is added).

[74] See, e.g. the work of Honguan Zhou, ShiliWu, JinYoung Joo, and others, published in *Cell Stem Cell* 4, May 8, 2009, pp. 381-384 (http://www.cell.com/cell-stem-cell/supplemental/S1934-5909(09)00159-3 In this study scientists have demonstrated that somatic cells (in the case, murine fibroblasts) could be fully reprogrammed into pluripotent stem cells by direct delivery of recombinant reprogramming proteins.