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MEDICALLY ASSISTED PROCREATION and THE PROTECTION OF THE EMBRYO IN VITRO in INTERNATIONAL CASE LAW

After 30 years of development, the New Reproductive Technologies have not only been acknowledged as an acceptable method to alleviate human infertility but they must also be regarded as an example of the importance of techno science as a fundamental tool of social and cultural transformation.

The role of international and comparative law in this field is precisely to make us aware that those changes in the cultural and legal construction of the family are now global and imply to find a fair balanced approach of all the interest concerned. This might explain the function of but also the difficulties faced by international jurisdictions in defining how to combine those interests with the diversity of existing domestic legislation.

Examining the international case law regarding the protection of the embryo in vitro, I would like to look on 3 examples, which describe the diversity and the complexity of the present situation. All of them focus on the application of regional instruments or legislation by « supra » national jurisdictions: two are dealing with European law and the third one concerns the application of the Inter american Convention on Human Rights. We can then see that the scope of the protection depends on the definition given to the embryo.
I. The legal definition of the embryo

The way the two European jurisdictions are approaching the issue -but not only this one- might be viewed as quite different and even opposed. In the field of Human Rights, the Court in Strasbourg is leaving a great margin of discretion to Members States while, in its own jurisdiction, the Court of Justice of the European Union is trying to reach common definition and interpretation to avoid unequal treatment. Nevertheless, both face difficulties in trying to reach a stable legal ruling, telling what might be the scope of the protection of the embryo in vitro, because courts are not prepared to solve societal issues when those issues are very controversial. It is quite clear that, on one hand, the ECHR never defined what an embryo is in regard with the Convention while, on the other hand, the Court of Justice till now only defined the embryo essentially in the perspective of applying the European directive on patenting biotechnology.

Paradoxically, the Inter-American Court of Human Rights chose a uniform approach to the definition of the human embryo with a similar reasoning to the one of the Court of Justice of the European Union. We will then examine more deeply these different approaches and case law.

A. How the absence of definition may work with the interpretation of the Convention?

In its interpretation of the ECHR, the Court always assumed a very careful approach on the issue of human embryo, taking into account the different opinions and legislations in member States. The reason of this attitude is certainly related to the fact the Court did not wanted to decide on abortion issues with an abstract view. And the same reason applied a few years later when cases related to other reproductive rights came to the Court.

1. Embryo and Abortion

Very early, the former Commission of Human Rights refused to examine in abstracto the compatibility of abortion laws with Article 2 of the Convention on the right to life.

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1 X v. Norway, no. 867/60, Commission decision of 29 May 1961, Collection of Decisions, vol. 6, p. 34, and X
In Brüggemann and Scheuten\(^2\), the Commission did not find it “necessary to decide, in this context, whether the unborn child is to be considered as ‘life’ in the sense of Article 2 of the Convention, or whether it could be regarded as an entity which under Article 8 § 2 could justify an interference ‘for the protection of others’ ”\(^3\). It expressed the opinion that there had been no violation of Article 8 of the Convention because “not every regulation of the termination of unwanted pregnancies constitutes an interference with the right to respect for the private life of the mother”\(^4\), while emphasizing: “There is no evidence that it was the intention of the Parties to the Convention to bind themselves in favour of any particular solution”\(^5\).

2. Other reproductive rights

a. In the Vo v. France case, a case concerning the right to life of an unborn child, the Court noted that « unlike Article 4 of the American Convention on Human Rights, which provides that the right to life must be protected “in general, from the moment of conception”, article 2 of the Convention is silent as to the temporal limitations of the right to life and, in particular, does not define “everyone” (“toute personne”) whose “life” is protected by the Convention. The Court has yet to determine the issue of the “beginning” of “everyone’s right to life” within the meaning of this provision and whether the unborn child has such a right »\(^6\). And, from the recapitulation of the case-law\(^7\), the Court deduced that « the unborn child is not regarded as a “person” directly protected by article 2 of the Convention and that if the unborn do have a “right” to “life”, it is implicitly limited by the mother’s rights and interests »\(^8\).

b. There is no clarification on this point in the European Convention on Biomedicine and Human Rights, which article 18 deals with research on embryos in vitro because « the Oviedo
Convention on Human Rights and Biomedicine is careful not to give a definition of the term “everyone”. Its explanatory report indicates that, in the absence of a unanimous agreement on the definition, the Member States decided to allow domestic law to provide clarification for the purposes of the application of that Convention (see paragraph 36 above).

The same is true of the Additional Protocol on the Prohibition of Cloning Human Beings and the Additional Protocol on Biomedical Research, which do not define the concept of “human being” (see paragraphs 37-38 above)\(^9\). But, although there is still an uncertainty about what the embryo is, « the Convention institutions have not, however, ruled out the possibility that in certain circumstances safeguards may be extended to the unborn child»\(^10\).

c. Regarding cases relating to the practice of IVF, in the case Evans v. United Kingdom\(^11\), the ECHR ruled 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 (see the above-mentioned X., Y. and Z judgment, § 44) »\(^12\).

Finally, in the cases of S.H. v. Austria\(^13\) and Costa and Pavan v. Italy\(^14\), which related respectively, to the regulation of IVF with respect to egg and sperm donation by third parties and pre-implantation genetic diagnosis, the ECHR did not refer to an alleged violation of a specific right of the embryo and therefore did not examine the issue of what an embryo is, simply reminding its ruling on the broad margin of discretion of Member States.

The reasoning is quite different in the case law of the CJEU because the ECHR refused to give an abstract definition explaining that « the Court is convinced that it is neither desirable, nor even possible as matters stand, to answer in the abstract the question whether the unborn child is a

\(^9\) para.84.
\(^10\) para.80.
\(^11\) case of Evans v. UK, n° 6339/05, judgment, 4th section, 7 march 2006 and Grand Chamber,10 April 2007.
\(^12\) idem para.62.
\(^13\) S H and others v Austria, n°57813/00 , 1st section, 1st april 2010 and Grand Chamber 3 nov.2011.
\(^14\) Costa et Pavan v Italy, n°54270/10, 2nd section, 28 August 2012.
person for the purposes of article 2 of the Convention »15 while in the Brüstle case16 the Court of Justice provides a common definition to Member States of the European Union. The Inter-American Court of Human Rights did the same way in the Case of Artavia Murillo and al. (“In Vitro Fertilization”) v. Costa Rica17.

B. An autonomous and uniform definition

1. The case law of the CJEU

a. In the Brüstle case, the Court was requested by a national jurisdiction, the German «Bundesgerichtshof», to interpret the concept of ‘human embryo’ within the meaning of and for the purposes of the application of article 6(2)(c) of the Directive 98/44/EC of 6 July 1998 on patenting biotechnology.

Although the court noted that «the text of the Directive does not define human embryo, nor does it contain any reference to national laws as regards the meaning to be applied to those terms», it nevertheless reached the conclusion that «it therefore follows that it must be regarded, for the purposes of application of the Directive, as designating an autonomous concept of European Union law which must be interpreted in a uniform manner throughout the territory of the Union »18.

Taking into consideration article 5(1) of the Directive, which provides that the human body at the various stages of its formation and development cannot constitute a patentable invention and article 6 which lists as contrary to ordre public or morality, and therefore excluded from patentability, processes for cloning human beings, processes for modifying the germ line genetic identity of human beings and uses of human embryos for industrial or commercial purposes and finally the fact that ,recital 38 in the preamble to the Directive states that this list is not exhaustive and that all processes the use of which offends against human dignity are also

15 id. note (6),para 85.
16 CJEU,(Grand Chamber), Olivier Brüstle , C34/10, 18 October 2011.
18 idem note (16),para.26.
excluded from patentability, the Court considered that « it follows that the concept of ‘human embryo’ within the meaning of article 6(2)(c) of the Directive must be understood in a wide sense. »¹⁹. Following this extensive approach, the Court then ruled that « accordingly, any human ovum must, as soon as fertilised, be regarded as a ‘human embryo’ within the meaning and for the purposes of the application of article 6(2)(c) of the Directive, since that fertilisation is such as to commence the process of development of a human being »²⁰. In addition, « that classification must also apply to a non-fertilised human ovum into which the cell nucleus from a mature human cell has been transplanted and a non-fertilised human ovum whose division and further development have been stimulated by parthenogenesis »²¹ while, regarding stem cells obtained from a human embryo at the blastocyst stage, the Court adopted the view that « it is for the referring court to ascertain, in the light of scientific developments, whether they are capable of commencing the process of development of a human being and, therefore, are included within the concept of ‘human embryo »²².

On a legal consideration, the Court is fully right when asserting that it « 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 (see, to that effect, Case C–506/06 Mayr [2008] ECR I–1017, paragraph 38) »²³. However, we have also to

¹⁹ ibid.para 34

¹⁰ This wide definition of the term embryo is in some way consistent with the even stricter decision of the Enlarged Board of Appeals of the European Patent Office in the Warf case (G 0002/06 (Use of embryos/WARF) of 25.11.2008) which came « to the conclusion that the legislators (both the legislator of the Implementing Regulations to 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 stem 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 53a EPC. The legislators have decided, remaining within the ambit of Article 53(a) EPC, and there is no room for manoeuvre » (para.31). For the enlarged Board of Appeals of the EPO, the « political » message is clear and does not leave any room left to interpretation. This is only in this way that it differs from the judgment of the CJEU.

²⁰ para 35.

²¹ para 36.

²² para 36.

²³ para 37.
consider the political impact of this first definition by a European court of what an embryo is and the fact that the CJEU adopted a broad definition will certainly have some consequence on the recurrent debate related to «this very sensitive social issue».

b. The International Stem Cell corporation/Comptroller General of Patents case offered an opportunity to obtain a first reaction to the Brüstle case law by suggesting a clarification and moderation of the CJEU’s approach to the patentability of stem cells and, by the way, to the definition of the human embryo. What was challenged with this new case is the legitimacy of the key criterion adopted in the Brüstle case and which in the eyes of the Court has been instrumental in its answers. This is the concept of "capable of commencing the process of development of a human being". This sentence means that any event, which starts the process of human life, must be regarded as falling within the definition of the human embryo and thus, because of the risk of harm -not to the body but at the dignity-, the invention which follows must be excluded from patentability. This is a kind of application of the precautionary principle to the field of ethics and this certainly the reason why the Court did not question the continuation and completion of the biological process. But is it a clear and operative criterion?

In the present case, the UK Intellectual Property Office’s decision rejected applications to patent a technology that produces stem cells from parthenotes on the grounds that, following Brüstle, the inventions entail the use of ‘human embryos’. On appeal to the English High Court, it was argued that parthenotes, which lack paternal DNA, are in fact incapable of becoming a human being and that therefore the restrictions on patentability elucidated in Brüstle do not apply. Given the uncertainty as to what the CJEU meant by ‘capable of commencing the process of development of a human being’ and whether it would have extended the concept of ‘human embryos’ to encompass parthenotes, the English High Court referred the issue to the CJEU for clarification. In its opinion, the Advocate-General of the Court recommended that the CJEU allow patenting of parthenotes by excluding them from the term ‘human embryos’. Allowing for future developments in stem cell technology, he added that parthenotes that acquire the

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24 Idem.
capability to develop into a human through genetic modification will not be excluded from the concept of ‘human embryos’ (and will therefore be excluded from patentability)\textsuperscript{26}. Following this opinion, the Court decided that “Article 6(2)(c) of Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions must be interpreted as meaning that an unfertilised human ovum whose division and further development have been stimulated by parthenogenesis does not constitute a ‘human embryo’, within the meaning of that provision, if, in the light of current scientific knowledge, it does not, in itself, have the inherent capacity of developing into a human being, this being a matter for the national court to determine”.

However, it is unlikely to consider that this “clarification” of the Brüstle jurisprudence based on the notion of “having \textbf{in itself} the inherent capacity of developing into a human being” will put an end to the discussion which is now entering into deep debate and controversy on what is an embryo as it is reflected in an other regional approach.

2. The jurisprudence of the Inter-American Court of Human Rights

a. A uniform interpretation

- The case submitted to the Court (Case of Artavia Murillo and al. (“In Vitro Fertilization”) v. Costa Rica)\textsuperscript{27} concerned the effects of the judgment delivered by the Constitutional Chamber of the Supreme Court of Costa Rica which declared unconstitutional Executive Decree No. 24029-S that regulated the In Vitro Fertilization (IVF) technique in the country on the basis of article 4.1 of the Inter-American convention of Human Rights which states that « every person has the right to have his life respected. This right shall be protected by law and, in general, from the moment of conception. No one shall be arbitrarily deprived of his life ». The Chamber interpreted article 4(1) of the Convention based on the understanding that the Convention requires the absolute protection of the embryo.


\textsuperscript{27} see note (17).
Before giving its own interpretation, the Inter-American court made it clearly understood that « the Court is the authorized interpreter of the Convention. Therefore, it deemed relevant to analyze whether the interpretation of the Convention by the Constitutional Court was admissible in light of said treaty and taking into account the different sources of pertinent international law. very subtle techno-scientific »28.

b. An indirect definition

- In bringing a uniform interpretation, the Court did not however elaborated a direct definition of what an embryo is but interpreting the words “person,” “human being,” and “conception” contained in article 4.1, it gave at least an indirect definition..

« The Court considers that the term “conception” cannot be understood as a moment or process exclusive of a woman’s body, given that an embryo has no chance of survival if implantation does not occur»29 which implies a clear distinction between two types of embryos, those who are implanted and those who are not.

- « Moreover, the Court indicated that the expression “every person” is used in numerous articles of the American Convention and the American Declaration. When analyzing these articles, it is not feasible to maintain that an embryo is the holder of and exercises the rights established in each of these article ». The Court then concluded that « it is not admissible to grant the status of person to the embryo»30.

- Finally, examining article 4 of the American Convention, article 3 of the Universal Declaration on Human Rights, article 6 of the International Covenant on Civil and Political Rights, the Convention on the Rights of the Child and the 1959 Declaration on the Rights of the Child. The Court ruled that « it is not possible to use any of these articles or treaties to substantiate that the embryo can be considered a person in the terms of article 4 of the Convention. Similarly, it is not possible to reach this conclusion from the commentaries or from the systematic interpretation of the

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28 Summary Newsletter of the Judgments issued by the Inter-American Court1 during its 97th Regular Period of Sessions, p 16, point 3.1.
29 idem p 17.
30 ibidem p 17-18, point 3.2.1.
rights recognized in the American Convention or in the American Declaration » 31.

Should we however really need a precise definition of the embryo to organise its legal protection with regard to IVF technology?

II. The legal protection of the embryo in vitro:

From the case-law examined, we can say that the protection of the embryo in vitro exists but that its extent is different in the field of Human Rights than it is in the field of patenting biotechnology. And the explanation for this difference relies on the methodology used to interpret the law. In the first case, the protection is based on a evolving interpretation of Human Rights Conventions while, in the second case, the extensive protection (in term of the prohibition of patents on human embryo) benefiting to the embryo is the effect of the broad definition of the human embryo which has been chosen by the Court of Justice of the European Union.

A. The Human Rights approach and the physical integrity of the embryo: a protection based on a principle of evolving interpretation of the Conventions

The jurisprudence of the ECHR as the one of the Inter-American Court is using the rule of evolving interpretation to elaborate the scope of the protection of the embryo in vitro. But, being essentially limited to the Costa Rica case, the 2012 judgment of the Inter-American Court is certainly clearer in the choices expressed by the Court than the jurisprudence of the ECHR is, leaving an important margin of discretion to Member States and fluctuating in time.

1. The jurisprudence of the ECHR

a. The unborn child does not benefit from the right to life

As we reminded above, in its early jurisprudence concerning abortion, the former European Commission of Human Rights « went on to examine whether article 2 was “to be interpreted: as not covering the foetus at all; as recognising a ‘right to life’ of the foetus with certain implied

31 id. p 19, point 3.2.5.
limitations; or as recognising an absolute ‘right to life’ of the foetus” (ibid. p. 251, § 17). Although it did not express an opinion on the first two options, it categorically ruled out the third interpretation, having regard to the need to protect the mother’s life, which was indissociable from that of the unborn child »

Although, « the unborn child is not regarded as a “person” directly protected by article 2 of the Convention and that if the unborn do have a “right” to “life”, it is implicitly limited by the mother’s rights and interests », the possibility to extend in certain circumstances safeguards to the unborn child is not, however, inexistent. « That is what appears to have been contemplated by the Commission in considering that “article 8 § 1 cannot be interpreted as meaning that pregnancy and its termination are, as a principle, solely a matter of the private life of the mother” (see Brüggemann and Scheuten, cited above, pp. 116-17, § 61) and by the Court in the above-mentioned Boso decision. It is also clear from an examination of these cases that the issue has always been determined by weighing up various, and sometimes conflicting, rights or freedoms claimed by a woman, a mother or a father in relation to one another or vis-à-vis an unborn child »

Furthermore, in the Vo case, it is clearly stated that « 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, notwithstanding an evolutive interpretation of the Convention, a “living instrument which must be interpreted in the light of present-day conditions” (see Tyrer v. the United Kingdom, judgment of 25 April 1978, Series A no. 26, pp. 15-16, § 31, and subsequent case-law). The reasons for that conclusion are, firstly, that the issue of such protection has not been resolved within the majority of the Contracting States themselves, in France in particular, where it is the subject of debate (see paragraph 83 below) and, secondly, that there is no European consensus on the scientific and legal definition of the beginning of life (see paragraph 84 below) »

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32 see note (6), para.77 .
33 idem, para.80 .
34 ibid. para.82 .
b. Then, what kind of protection for the embryo in vitro?

- Regarding cases relating to the practice of IVF, the most pertinent case is Evans v. U-K\(^{35}\) which concerns the applicant's partner withdrawal to a continuing IVF treatment and her request that the already procreated embryos in vitro should be destroyed. « In its judgment of 7 March 2006, the Chamber observed that in Vo v. France [GC], no. 53924/00, § 82, ECHR 2004-VIII, the Grand Chamber had held that, in the absence of any European consensus on the scientific and legal definition of 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, as was made clear by the domestic courts in the present applicant’s case, 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. There had not, accordingly, been a violation of that provision »\(^{36}\).

Then, restating the wide margin of appreciation given to Member States in sensitive moral and ethical issues, « the Grand Chamber, like the Chamber, considered that the above margin must in principle extend both to the State’s decision whether or not to enact legislation governing the use of IVF treatment and, having intervened, to the detailed rules it lays down in order to achieve a balance between the competing public and private interests »\(^{37}\). It then came to the conclusion that « the Grand Chamber, for the reasons given by the Chamber, finds that the embryos created by the applicant and J. do not have a right to life within the meaning of article 2 of the Convention, and that there has not, therefore, been a violation of that provision»\(^{38}\).

- Other cases, the cases of S.H. v. Austria\(^{39}\), Costa and Pavan v. Italy\(^{40}\) and Knecht v. Romania\(^{41}\) relate respectively, to the regulation of IVF with respect to egg and sperm donation by third

\(^{35}\) see note (6), para.82.
\(^{36}\) see note (11),para.54.
\(^{37}\) see note (34).
\(^{38}\) see note (6), para 56 .
\(^{39}\) see note (13)  .
\(^{40}\) see note (14).
\(^{41}\) Case of Knecht v. Romania, 2 oct.2012, n° 10048/10,3rd section.
parties, to pre-implantation genetic diagnosis and to the impossibility for the claimant to retrieve and transfer her embryos. But their interest is limited for the issue of the protection of the embryo in vitro because the ECHR did not refer in those cases to an alleged violation of a specific right of the embryo but to the respect for private life of the expecting parents. The Court however reaffirmed its view that « the Court’s task is not to review the relevant legislation or practice in the abstract; it must as far as possible confine itself, without overlooking the general context, to examining the issues raised by the case before it (see Olsson v. Sweden (no. 1), 24 March 1988, § 54, Series A no. 130). Consequently, the Court’s task is not to substitute itself for the competent national authorities in determining the most appropriate policy for regulating matters of artificial procreation, in respect mainly of procedures to be followed or authorities to be involved and to what extent, especially since the use of IVF treatment gave rise then and continues to give rise today to sensitive moral and ethical issues against a background of fast-moving medical and scientific developments. It is why in such a context the Court considered that the margin of appreciation to be afforded to the respondent State is a wide one (see S.H. and Others v. Austria, cited above, § 97). The State’s margin in principle extends both to its decision to intervene in the area and, once it has intervened, to the detailed rules it lays down in order to achieve a balance between the competing public and private interests (see Evans, cited above, § 82) »

-The Parillo case: an interesting case for its legal approach.

The fact are as follows: in 2002, the applicant and her partner, who has since died, had recourse

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42 idem,para.59
43 Parrillo v. Italy (no. 46470/11). idem,para.59

ibidem

The European Court of Human Rights (ECHR, Grand ch. case. Parillo v Italy, August 27, 2015, No. 46470/11) held that " the right invoked by the applicant to donate embryos to scientific research is not one of the core rights attracting the protection of Article 8 of the Convention as it does not concern a particularly important aspect of the applicant’s existence and identity. » (para174) and without having to rule on the question of the beginning of human life but «Having regard to the economic and pecuniary scope of Article 1 of Protocol 1 human embryos cannot be reduced to “possessions” within the meaning of that provision » (para.215).
Medically Assisted Procreation

to medically assisted procreation techniques and they underwent *in vitro* fertilisation treatment. Five embryos were produced. The applicant wishes to donate the in vitro embryos to assist scientific research into ways of curing diseases that are difficult to treat. However, a law which entered into force in Italy in 2004 (Law no. 40/2004) prohibits experiments on human embryos, even for the purposes of scientific research. The applicant submits that the embryos in question were created prior to the entry into force of Law no. 40/2004, and that it was therefore entirely legal for her to store the embryos by means of cryopreservation without having them implanted immediately. She relies in particular on article 1 (protection of property) of Protocol No. 1 to the Convention, complaining that Law no. 40/2004 prohibited her from donating her embryos for scientific research, obliging her to keep them in a state of cryopreservation.

The case interest relies in the fact that it raises the reverse issue to the one of embryo protection which is the right to do embryo research. The legal argument brought by the applicant to the Court is also particularly provocative because it relies on the protection of property. All these reasons may explain that the case was relinquished by the Chamber 44 in favour of the Grand Chamber in January 2014. On June 2014, the Grand Chamber held its hearing 45 and finally gave its decision on 27th August 2015 (see note 43).

2. The judgment of 28th novembre 2012 of the Inter-American Court of Human Rights (IACHR) 46

Unsing different methods of interpretation and basing broadly its view on an international comparative law analysis, the Court of San Jose reached a conclusion that the protection of the Embryo *in vitro* is not absolute but based on the notion of graduality.

a. The systematic and historic interpretation

Noting that the Constitutional Chamber and the State of Costa-Rica based their arguments to

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44 ECHR, Parrillo v. Italy (relinquishment) - 46470/11 Decision 28.5.2013 [Section II], January 2014.
justify the absolute protection of human embryo on an interpretation of the Universal Declaration of Human Rights, the International Covenant on Civil and Political Rights, the Convention on the Rights of the Child and the 1959 Declaration on the Rights of the Child. The IACHR produced a systematic and historic interpretation of those instruments which resulted in the conclusion that « it is not possible to use any of these articles or treaties to substantiate that the embryo can be considered a person in the terms of article 4 of the Convention. Similarly, it is not possible to reach this conclusion from the commentaries or from the systematic interpretation of the rights recognized in the American Convention or in the American Declaration »

b. The evolutive interpretation

Then, the Court examined the case on an evolutive interpretation ground because it considered that « in the instant case, the evolutive interpretation is particularly relevant, bearing in mind that IVF is a procedure that did not exist when the authors of the Convention adopted the content of article 4(1) of the Convention » which states that « Every person has the right to have his life respected. This right shall be protected by law and, in general, from the moment of conception. No one shall be arbitrarily deprived of his life »

There again, the Court, referring to the Oviedo Convention, several cases of the European Court of Human Rights and a judgment of the Court of Justice of the European Union concluded that the regulatory trends in international law do not lead to the conclusion that the embryo should be treated in the same way as a person, or that it has a right to life. More precisely, regarding IVF regulations in the Americas, « the Court considered that, even though there are few specific legal regulations on IVF, most of the States of the region allow IVF to be practiced within their territory. This means that, in the context of the practice of most States Parties to the Convention, it has been interpreted that the Convention allows IVF to be performed. The Court deemed that this practice by the States is

47 idem,para.244.
48 idem,para.246.
50 idem,para.247-252.
related to the way in which they interpret the scope of article 4 of the Convention, because none of the said States have considered that the protection of the embryo should be so great that it does not permit assisted reproduction techniques and, in particular, IVF. Thus, this generalized practice is associated with the principle of gradual and incremental—rather than absolute—protection of prenatal life and with the conclusion that the embryo cannot be understood as a person »\(^{51}\).

c. As another way of reasoning, the Court focused on the necessity to respect the principle of most favorable interpretation regarding the object and purpose of the treaty. Firmly asserting that « ...the purpose of article 4(1) of the Convention is to safeguard the right to life, without this entailing the denial of other rights protected by the Convention», the Court deduced that « ...the object and purpose of the expression “in general” is to permit, should a conflict between rights arise, the possibility of invoking exceptions to the protection of the right to life from the moment of conception. In other words, the object and purpose of article 4(1) of the Convention is that the right to life should not be understood as an absolute right, the alleged protection of which can justify the total negation of other rights»\(^{52}\).

Finally, as a general conclusion, the Court, « ...having used these different methods of interpretation », considered that they « ...have led to similar results according to which the embryo cannot be understood to be a person for the purposes of article 4(1) of the American Convention. In addition, after analyzing the available scientific data, the Court has concluded that “conception” in the sense of article 4(1) occurs at the moment when the embryo becomes implanted in the uterus, which explains why, before this event, article 4 of the Convention would not be applicable. Moreover, it can be concluded from the words “in general” that the protection of the right to life under this provision is not absolute, but rather gradual and incremental according to its development, since it is not an absolute and unconditional obligation, but entails understanding that exceptions to the general rule are admissible »\(^{53}\).

\(^{51}\) id., para 256.

\(^{52}\) ibid. para 258.

\(^{53}\) para. 264.
While under the case law of the ECHR, the scope of the legal protection of the embryo is relying on the wide margin of appreciation left to Member States in areas where there is no broad consensus, in the law of the European Union, the scope of the legal protection is limited to the fields which fall within the EU Jurisdiction. 

B. The European Union Law: a broad protection limited to biotechnology patents

Thus far, the Court of Justice of the European Union (CJEU) has been offered little opportunity to pronounce itself on matters related to embryo protection. In the case of The Society of Unborn Children Ireland the court ruled that it had no jurisdiction to deal with a case of restriction of information on abortion services while in the Sabine Mayr case, the Court held that the protection of EU law of pregnant workers against dismissal extends to women who are in ‘an advanced stage of in vitro fertilization treatment’ but, the CJEU made very clear that it gave a ‘legal interpretation’ of the relevant Directive 92/85 only. Finally in the Brüstle case, the court insisted to remind its previous ruling that 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 (see, to that effect, Case


In a judgment of 4 October 1991 on the questions referred under Article 177 of the EEC Treaty, following the Supreme Court or Ireland’s judgment, the Court of Justice of the European Communities ruled that the medical termination of pregnancy, performed in accordance with the law of the State in which it is carried out, constitutes a service within the meaning of Article 60 of the Treaty. However it found that the link between the activity of the student associations and medical terminations of pregnancy carried out in clinics in another member State was too tenuous for the prohibition on the distribution of information to be capable of being regarded as a restriction on the freedom to supply services within the meaning of Article 59 of the Treaty. The Court did not examine whether the prohibition was in breach of Article 10 (art. 10) of the Convention. In the light of its conclusions concerning the restriction on services it considered that it had no jurisdiction with regard to national legislation "lying outside the scope of Community law".

55 Idem.

56 Sabine Mayr, C-506/06, judgment [GC] of 26 February 2008 [2008] ECR I-01017, para. 53-

54.

57 idem, para. 38.
C-506/06 Mayr [2008] ECR I-1017, paragraph 38).».

So, it is only within the field of patenting biotechnology that the protection of the embryo received some legal development in the law of the European Union. It means that the definition of the embryo as given by the CJEU takes its scope in the context of the other questions asked by the German supreme court. Those questions were:

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 [the Directive], 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:

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

– or because the patent concerns a process for which such a product is needed as base material?’

1. The meaning of the expression “uses of human embryos for industrial or commercial purposes”

1) The answer of the Court does not suffer any ambiguity. Because, « clearly the grant of a patent implies, in principle, its industrial or commercial application » 58, « the answer to the second question is therefore that the exclusion from patentability concerning the use of human embryos for industrial or commercial purposes in article 6(2)(c) of the Directive also covers use for purposes of scientific research, only use for therapeutic or diagnostic 59 purposes which is applied to the human embryo and is useful to it being patentable »..But, responding categorically positively to the second question, the Court nonetheless opens (willingly?) the way to an exception.

58 see note (16), para.41. For further explanation on the rereasoning of the Court, refer to para.42-45.
59 idem, para 46.
a) In principle, patentability is excluded

The Court's reasoning is built in two stages:

- First, it states that "the grant of a patent implies, in principle, its industrial and commercial exploitation" and that this « interpretation is supported by recital 14 in the preamble to the Directive. By stating that a patent for invention ‘entitles [its holder] to prohibit third parties from exploiting it for industrial and commercial purposes’, it indicates that the rights attaching to a patent are, in principle, connected with acts of an industrial or commercial nature""60; 

- As a second step, the Court goes on to say that « although the aim of scientific research must be distinguished from industrial or commercial purposes, the use of human embryos for the purposes of research which constitutes the subject-matter of a patent application cannot be separated from the patent itself and the rights attaching »61.

b. The exception: patentability is legal for therapeutic or diagnostic purposes

Regarding the prohibition of patents on human embryo, the Court reminds us52 the existence of an exception in favour of « inventions for therapeutic or diagnostic purposes which are applied to the human embryo and are useful to it ».

Consequently, might we deduce that this exception would allow an applicant for a patent related to a process to isolate stem cells to claim that the patent covers therapeutic applications on embryos to exclude the prohibition to patent process that would use those embryos?

In our view, a positive answer would necessary mean that the invention should meet another condition put forward by the Court in its reply to the third part of the question.

2. Is technical teaching to be considered unpatentable?

Is an invention excluded from patentability, even though it does not affect the use of human embryos, if it concerns a product whose production requires the prior destruction of embryos?

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60 idem, para 41 and 42.
61 idem , para.43.
62 para.44.
The positive response of the Court is not surprising as it is consistent with the views it adopted previously and because it is reinforced by the principle of the effectiveness of Community law.

**a. The legal consistency with the answers given to the other questions**

Noting that “the removal of a stem cell from a human embryo at the blastocyst stage entails the destruction of that embryo”\(^{63}\), the Court relies « on the same grounds as those set out in paragraphs 32 to 35 above, (to say 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. In that case too, the view must be taken that there is use of human embryos within the meaning of article 6(2)(c) of the Directive. The fact that destruction may occur at a stage long before the implementation of the invention, as in the case of the production of embryonic stem cells from a lineage of stem cells the mere production of which implied the destruction of human embryos is, in that regard, irrelevant »\(^{64}\).

**b. The principle of the effectiveness of Community law**

This principle, which occurs in all areas of EU law, aims to promote an operational interpretation of the texts that give to their application the most effective way.

Following this rule, « not to include in the scope of the exclusion from patentability set out in article 6(2)(c) of the Directive technical teaching claimed, on the ground that it does not refer to the use, implying their prior destruction, of human embryos would make the provision concerned redundant by allowing a patent applicant to avoid its application by skilful drafting of the claim »\(^{65}\).

Again, the Court may consolidate its reasoning based on the jurisprudence of « the Enlarged Board of Appeal of the European Patent Office which reached the same conclusion when asked about the interpretation of Rule 28(c) of the Implementing Regulations to the CGEP, the wording...
of which is identical to that of article 6(2)(c) of the Directive (see decision of 25 November 2008, paragraph 22, referred to in paragraph 45 above) »^{66}.

**Conclusion:**

The interest of the issue raised by this study is not only to reply to the concrete question: « what is the legal basis and scope of the protection of the embryo in vitro?».

It is to suggest a broader question: does a global world imply a global approach to sensitive ethical, legal and social issues?

This is a central question for International Law to determine its objective and to search methods to comply with it.

It is a key issue in term of policy making both in the field of Human Rights and in Intellectual Property Law to know if those two legal systems should either cooperate or be harmonized at least at the international level and according to which mechanisms.

Finally, it is a human concern to be aware that progressively the world in which we live is gradually but substantially changing in term of governance, rights, interests and capacity to maintain a peaceful but efficient way to solve ethical, legal as well as other types of controversies.

^{66} para.51.
Medically Assisted Procreation