

ASPECTS OF HUMAN EMBRYO STATUS IN INTERNATIONAL LAW

Izabela Bratiloveanu, PhD, University of Craiova

Abstract: "The race to be the first should be avoided, especially when germinal modification is proposed", reported the International Bioethics Committee (IBC) in its 2015 Report on Updating Its Reflection on Human Genome and Human Rights. Recent developments in genetics have revealed remarkable scientific, diagnostic and therapeutic perspectives, but also unprecedented risks, making the difficult topic on the legal condition of the human embryo more present than ever. In this study, we made reference to the relevant soft law instruments of the Council of Europe and to the Convention on Human Rights and Biomedicine signed in 1997. In the context of a lack of a unanimously accepted scientific or legal definition of when the life begins, our study examines the jurisprudence in the matter of the European Court of Human Rights and the Court of Justice of the European Union.

Keywords: human embryo; the right to life; European Court of Human Rights; The Court of Justice of the European Union; genetic engineering.

There is no doubt that "science has multiplied the creative powers of the human being and the social progress, but it has also created destructive risks to man and the environment, to the genetic diversity of nature, even to the survival of the species"¹. The rapid evolutions in the genetics field pose new and complex ethical and political issues for individuals and society and a legal response is needed in order to avoid inappropriate use of new technologies². This concern is particularly driven by two techniques: human germline interventions and human reproductive cloning.

In November 2018, at the Second International Summit on Human Genome Editing, organized by the University of Hong Kong, He Jiankui announced that he had used the CRISPR-Cas9 gene editing technique to modify the CCR5 gene in several embryos created by IVF for couples of HIV-positive parents, preserving it as an HIV vaccine study, the Chinese researcher becoming the creator of the first generation of genetically modified children in the world³. The reaction of the Council of Europe's Bioethics Committee (DH-BIO), which represents 47 European countries, has not been delayed. In the "Ethics and Human Rights" Statement of 30 November 2018, the Bioethics Committee reiterated the "Statement on Genom Editing Technologies" adopted in 2015. DH-BIO, which is subordinated to the Steering Committee for Human Rights, was convinced that "the Oviedo Convention provides principles that could be used as a reference for the international debate on the issues raised by recent technological developments". Particular consideration was given to art. 13 of the Convention on Human Rights and Biomedicine⁴ (the so-called "Oviedo

¹ Gh. Scripcaru, V. Astărăstoae, A. Ciucă, C. Scripcaru, *Introducere în biodrept – de la bioetică la biodrept*, Lumina Lex Publishing House, Bucharest, 2003, p.135.

² R. Andorno, *Biomedicine and international human rights law: in search of a global consensus*, BWHO no. 80/2002, p. 959.

³ <http://www.europalibera.org/a/29630001.html>, last access on December 1, 2018.

⁴ Romania signed the Oviedo Convention on 4 April 1997.

Convention") which limits the scope of interventions to the human genome to preventive, diagnostic and therapeutic interventions and prohibits any intervention aimed at introducing a change in the genome of a descendant. In 2015, in response to advances in genetics and genomics, UNESCO's International Bioethics Committee (IBC) issued a report recommending a moratorium on germinal human genome engineering, "at least until their safety and long-term consequences be better understood"⁵. Interventions on the human genome raise concerns about safety due to off-target effects of gene editing⁶ and human rights, notably the effects on future generations⁷. According to EASAC, "These applications pose many important issues, including the risks of inaccurate or incomplete editing, the difficulty of predicting harmful effects, the obligation to consider both the individual and future generations who will carry the genetic alterations, and the possibility that biological enhancements beyond the prevention and treatment of disease could exacerbate social inequities or be coercive. It would be irresponsible to proceed unless and until the relevant ethical, safety and efficacy issues have been resolved and there is a broad societal consensus"⁸. In its Recommendation 2115 (2017)⁹, the Parliamentary Assembly of the Council of Europe urged the Member States to ratify the Oviedo Convention or, at the very least, to implement a national ban on the establishment of a human germ line or embryonic subject of intentional genome editing.

Who are the holders of the right to life? Where does the protection of this right start and where does it end? What is a human embryo? Answers to these questions are particularly important because it has been sustained the fact that if the human embryo is alive, it should not be deprived of the possibility of development, and therefore research on embryos should not be allowed, nor the destruction of the embryos. Other voices said that, without denying that the embryos are alive, they are not yet human beings, and if one could decide when an embryo becomes a person, one might decide when they could be used for research and not.

Concerning the protection of the human embryo and the prevention of abusive use of genetic manipulation, the Council of Europe has issued several recommendations to which the European Court of Human Rights refers in its case-law. Recommendation 934 (1982) on genetic engineering defines this notion as "the application of new techniques of artificial recombination of genetic material from living organisms" and proposes a set of measures, in particular the recognition of a right to a genetic patrimony that does not either artificially manipulated with the exception of therapeutic purposes. Recommendation 1046 (1986) draws attention to the need to define the biological status of the human embryo and considers that the human embryo and fetus must be treated with respect for human dignity. The Assembly estimates that the use of the embryo or fetus and their tissues should be limited to diagnostic or therapeutic purposes, including an annex with rules to be observed for this purpose. In the Assembly's view, the following facts are considered to be manipulations or deviations from techniques involving the use of embryos and fetuses or their tissues for therapeutic purposes: the creation of an identical human being through cloning or other methods, including selection of the race; implanting an embryo in an animal's uterus or vice versa; fusion of human gametes with those of an animal; sperm embryo creation from different individuals;

⁵ International Bioethics Committee (IBC), Report of the IBC on Updating Its Reflection on the Human Genome and Human Rights, Paris, 2 octombrie 2015.

⁶ Affecting other genes.

⁷ Changing the genome means changing the common inheritance of humanity. Rapporteur Petra De SUTTER, Report of the Committee on Social Affairs, Health and Sustainable Development. The use of the new genetic technologies in human beings, p. 9.

⁸ March 2017, EASAC Report on genome editing, p.2.

⁹ Assembly debate on 12 October 2017 (35th Sitting). Text adopted by the Assembly on 12 October 2017 (35th Sitting).

fusion of embryos or other operations likely to produce chimeras; ectogeneza; creating children of the same sex persons; the choice of sex through genetic manipulation for non-therapeutic purposes; creating identical twins; research on viable human embryos; experimenting with live embryos and maintaining embryos in vitro over the 14th day after fecundation. The Recommendation 1100 (1989) on the use of human embryos and fetuses in scientific research provides that the human embryo, although developing in successive phases bearing different names, exhibits a progressive differentiation of its organism and maintains its biological and genetic identity. The Annex to the same Recommendation contains rules on scientific research and/or experimentation with gametes, human embryos and foetuses and the donation of the elements of this human material.

So far, there is no unanimously accepted definition (scientific, legal) regarding the moment when life begins. At the level of the Member States of the Council of Europe, most of them do not provide a legal definition of the human embryo and among the definitions given by some States¹⁰ we can see considerable differences.

If art. 4 par. (1) of the American Convention on Human Rights¹¹ provides that everyone's right to life must be protected "in general from the moment of conception", the European Convention on Human Rights does not define "life" or the "right to life"¹². Facing such a silence, the European Court refuses to rule on the definition of these terms and prefers to make reference to the laws of the States concerned to rule on this matter¹³.

In the jurisprudence of the European Commission of Human Rights, the aspect of the lower limit of the right to life has arisen particularly in relation to legislation on abortion. Therefore, in the case *X. vs. United Kingdom*¹⁴, the applicant complained against the authorization given to his wife pursuant to the English law to practice the interruption of pregnancy without asking for his consent as well. The Commission considered that the term "any person" appearing in art. 1, art.2, art.5, art.6, art.8, art.11 and art. 13 of the Convention, can only refer to a born person. The child to be born is not a "person", in the general sense given to this term and the context in which it is used in the conventional provision; art. 2

¹⁰Austria, Germany, Spain.

¹¹ Adopted at the Inter-American Specialized Conference on Human Rights, San José, Costa Rica, 22 November 1969.

¹²To be noted, the Constitutions of certain States establish the moment of conception as the lower limit of the right to life. By the Eighth amendment of the Irish Constitution, adopted following the Referendum in 1983, it was introduced art. 40.3.3. in the Irish Constitution, which provides: "*The State acknowledges the right to life of the unborn and, with due regard to the equal right to life of the mother, guarantees in its laws to respect, and, as far as practicable, by its laws to defend and vindicate that right*". With regard to this amendment it was stated that it is "a decision by the people to insert into the Constitution a specific guarantee and protection for a fundamental right perceived to be threatened by developments in the societies of countries outside Ireland". (See R. Lawson, *The Irish abortion cases: European limits to national sovereignty?* in EJHL no. 1/1994, p.167). Another example, in South America this time, art. 19 in the Constitution of Chile of 1980 provides that "Artículo 19. La Constitución asegura a todas las personas: 1°. El derecho a la vida y a la integridad física y psíquica de la persona. La ley protege la vida del que está por nacer." ("*The law provides to all persons: 1°. The right to life and physical and psychic integrity of the person. The law protects the life of the unborn*"). In Chile, the former military dictator Augusto Pinochet incriminated abortion in all its forms in 1989, a law that remained in force until 2017 when, by a draft of a law proposed by President Michelle Bachelet, abortion was decriminalized in three situations: 1) when the woman is in vital danger, so that the termination of pregnancy avoids a danger to her life; 2) the embryo or foetus has an acquired or genetic congenital pathology, incompatible with independent life outside the uterus, in any case of vital nature; 3) is the result of rape, but does not exceed 12 weeks of pregnancy.

¹³H. Bandolo Kenfack, *Le droit à la vie de l'enfant à naître face au pluralisme juridico-culturel européen: essai d'une conciliation à partir de la théorie de la marge nationale d'appréciation*, RDUS, vol. 45, no. 3/2005, p. 481.

¹⁴Commission EDH, decision of 13 May 1980, application no. 8416/1979.

cannot be interpreted as recognizing the foetus a right to life of absolute nature¹⁵. As in the case it was about a therapeutic abortion, the Commission prudently stated that the authorization of the interruption of pregnancy, granted by the British authorities is compatible with art. 2 par. 1 of the Convention because, assuming that this provision applies in the initial stage of pregnancy, the right to life of the foetus suffers an implicit limitation in order to protect the life and health of the woman.

Subsequently, in the case *R.H. vs. Norway*¹⁶, the Commission pointed out that it did not have to decide whether the foetus may enjoy a certain protection under art. 2 of the text of the Convention, but it did not exclude the possibility that in certain circumstances such protection may be recognized, although it admitted that between the Contracting States there were a considerable divergence of views on whether or to what extent art. 2 protects the unborn life. The applicant was the life partner of the woman to whom the Norwegian courts had authorized the request for termination of the pregnancy on social grounds. In this case, the Commission considered that in such a delicate sphere as the abortion, where national laws differ considerably, the States must exercise some discretionary power.

In the case *Open Door and Dublin Well Woman v. Ireland*¹⁷, the Court found that art. 10 of the Convention was violated and it noted that in this case it was not called to determine whether the Convention guarantees a right to abortion or whether the right to life (article 2 of the Convention) also applies to the foetus¹⁸.

Representative in this matter is the Judgement pronounced by the Grand Chamber of the Court in the case *Vo v. France*¹⁹. In this case, the applicant of Vietnamese origin invoked the violation of article 2 of the Convention, because the act of a doctor responsible for the death of her child in utero was not qualified by the French courts as the crime of negligent homicide. In her opinion, the moment when life begins has a universal meaning and definition, a fact which is scientifically proved that life begins from the moment of fertilization. Therefore, she sustained that the unborn is a person, not an object, otherwise one could” conclude that in this case she did not lose anything”²⁰ and ”such an argument is unacceptable to a pregnant woman”²¹. Unlike the aforementioned cases, this time, the court in Strasbourg faced a new problem: the termination of pregnancy had been caused by the errors committed by the treating physician, which required a therapeutic abortion.

Following the examination of the case, the court stated that the issue regarding the moment when the right to live begins is within the margin of appreciation of the States, thus considering that States should enjoy this margin of appreciation, even in the context of an evolutive interpretation of the Convention, as a “living instrument which must be interpreted in the light of present-day conditions”²². In formulating this conclusion, the Court relied on two arguments: the problem was not solved in most States and especially in France, and the scientific and legal definition of the beginning of life is not the subject of a European consensus. The Court stated that in the best case it should be considered a common denominator among states the fact that the embryo belongs to the human race. In the sense of the Grand Chamber “the potentiality of that being and its capacity to become a person [...]

¹⁵ J.F. Renucci, *Tratat de drept european al drepturilor omului*, Hamangiu Publishing House, Bucharest, 2009, p.103.

¹⁶Commission EDH, decision of 19 May 1992, application no. 17004/1990, available on <https://www.globalhealthrights.org/wp-content/uploads/2016/12/H.-v.-NORWAY.pdf>, last accessed 1 December 2018.

¹⁷Decision of 29 October 1992, applications no. 14234/88, 14235/88.

¹⁸*Idem*, § 66.

¹⁹Application no. 53924/00, decision of 8 July 2004.

²⁰ §47.

²¹*Idem*.

²² §82.

require protection in the name of human dignity, without making it a “person” with the “right to life” for the purposes of Article 2”²³. Therefore, recognizing the lack of consensus at the European level on this issue, the court considered that it was not desirable and not even possible to answer in abstract terms to the question whether the unborn is a person. The conclusion is of cautious nature: there was no violation of article 2, even assuming that this provision would be applicable in the case. In line with the judgement given in the case *Vo v. France*, the jurisprudence of the court in Strasbourg is a constant one: until present time the Court has been cautious in defining the human embryo as a person, by making reference to the doctrine of the national margin of appreciation. The principle of human dignity is the one which legitimizes a minimal common protection of the embryo/foetus: human dignity is identified as being the common ground of protection acknowledged because the embryo/foetus “belongs to the human race”²⁴. As ascertained in French doctrine, the positive law must recognize “humanity beyond the strict notion of the person in a legal sense, satisfactory only when it comes to patrimonial or filiation aspects, and not when the existence and dignity of the human being must be respected”²⁵.

On 27 August 2015, the Grand Chamber of the Court pronounced in the case *Parillo v. Italy*²⁶ for the first time on the question of whether the right to respect for private life includes the right to dispose of embryos created by in vitro fertilization with a view for donation to scientific research, the answer given by the European Court being affirmative²⁷. The case raises concerns with regard to the legal status of the embryo and with regard to the consequences of this status, including the rights, the obligations and the liability of those who have a genetic connection with the embryo or who have committed themselves to becoming potential parents following the in vitro treatment which has the result of creating embryos²⁸.

In 2002, the applicant Adelina Parillo, together with her partner, turned to the in vitro fertilization technique which resulted in five embryos that were cryopreserved. Because in 2003 the applicant's partner died as a result of a terrorist attack in Nasiriya (Iraq), the

²³ §84. Under Romanian law, the legal personality is the general and abstract ability to be a holder of rights and obligations, being conferred by law. Representing the man's ability to be theholder of civil rights and obligations, the ability of use expresses the very essence of man to be an individual subject of civil law. The capacity of use begins at the birth of the person and ends upon his/her death (art. 35of the Civil Code). The time of the child being alive is indifferent for obtaining the ability of use, having this capacity even when it died as soon as it was born (*licet illico postquam in terram cecidit, vel in manibus obstetricis decessit*). Art. 36 entitled “The rights of the child conceived” stipulates that the rights of the child are recognized from its conception, but only if it is born alive. It is considered as the legal time of conception the period of time between three hundred and one hundred and eightieth day before the child is born; it is calculated daily. The exception of acquiring the anticipated capacity of use was known from Roman law, being expressed in the adage *infans conceptus pro nato habetur quotiens de commodis eius agitur*(the child conceived is considered born when it comes to its rights). To apply the exception to the acquisition of the capacity of use from conception, the conditions are the following: to be about its rights and to be born alive. Anticipated capacity of use is recognized for the child who is born alive, therefore it is conditional. The child born dead does not acquire the anticipated capacity of use, this circumstance having the meaning of a cancellation condition. Very precisely said, it is not about granting the ability of use to the child conceived, but about retroactive recognition, even from conception, of this capacity with regard to the child born alive. Both human dignity and the right to life are supreme values of the Romanian State, according to art. 1 par. (3) of the Constitution. Therefore, guaranteeing these values allows a legal protection of the human embryo, even if it does not have legal personality.

²⁴Ibidem.

²⁵ M. Herzog-Evans, *Homme, homme juridique et humanité de l'embryon*, RTD civ. 2000, p.66.

²⁶ Application no. 46470/11.

²⁷ See §159 where it is stated that “the Court has thus concluded that the applicant's ability to exercise conscientious and informed choice as to the fate of her embryos concerns an intimate aspect of her personal life and as such enters into the scope of its right to self-determination”.

²⁸ J. Giles, S. Lee, *Parillo v. Italy: Is there life in the European Convention of Human Rights?*, Oxford Journal of Law and Religion, Vol.5, no.1/2016, p.162.

implantation of embryos has not taken place. In this case, the applicant sustained that the interdiction laid down in Art. 13 of Law no. 40/2004 to donate for the purpose of scientific research the embryos conceived through medical assisted reproduction was incompatible with art. 8 of the Convention and Art. 1 of Protocol No. 1 to the Convention. The Court in Strasbourg ruled by 16 votes in favour and one against that the right to private life was not violated and in unanimity for the non-violation of her ownership right.

The interference in art. 8 of the Convention being provided for by law, the Grand Chamber examined the legitimacy of the purpose pursued and the necessity of measure in a democratic society. In the Court's view, protecting the right to life of the embryo" may be connected to the purpose of "moral protection of the rights and freedoms of others"²⁹, but without clarifying the question of whether the term "others" applies to the human embryo. In this respect, in his concurring opinion, Judge Pinto de Albuquerque criticized the argument of the majority as being contradictory on a logical plan because "the majority admits, on the one hand, that the embryo is "another" within the meaning of Art. 8§2 of the Convention because the protection of its life potential can be correlated with the purpose of protecting the "rights and freedoms of others" and, on the other hand, "the same majority declares that this recognition does not imply any reasoning on the part of the Court in order to establish if the term "others" includes the human embryo", such a contradiction between statements being "so obvious that it becomes irremediable"³⁰.

Furthermore, the Court considered the grounds invoked as being relevant and sufficient in order to justify interference in line with Art. 8 par. (2) of the Convention text. To decide in this manner, the Grand Chamber took into consideration the wide margin of appreciation left to Italy³¹ in this case with regard to the fact that the right to donate embryos for scientific research purposes "is not part of the nucleus of fundamental rights protected by art. 8 of the Convention because it is not a particularly important aspect of the applicant's existence and identity"³², and the donation of embryos which are not intended for implantation raises "delicate moral and ethical issues"³³ and "there is no consensus in this field at European level"³⁴. In addition, the Court considered that the interdiction was the result of a broad legislative process that took into consideration various interests involved. As well, the Court considered that "the choice to donate embryos [...] for scientific research purposes results exclusively from the will of the applicant whose partner died"³⁵ and it establishes the condition of existence of the choice of both parents to entrust them to scientific research.

In his concurring opinion, Judge Pinto de Albuquerque contradicts the opinion of the majority by pointing out that States should have "only a limited margin of appreciation on the fundamental issues related to the existence and the identity of the human being"³⁶ and draws attention to the fact that "the beginning and the end of human life are not political issues which need to be left to the Member States"³⁷, because otherwise "the Court would give up the most important of its tasks, namely the protection of human beings against any form of instrumentalization"³⁸.

²⁹ Provided by art. 8 par. (2) of the Convention.

³⁰ §31. The confusion of the majority's reasoning is also highlighted in the partially dissenting common opinion of Judges Casadevall, Ziemele, Power-Forde, De Gaetano and Yudkiska.

³¹ §176.

³² §174.

³³ §176.

³⁴ *Ibidem*.

³⁵ §196.

³⁶ §43.

³⁷ §43.

³⁸ §26.

The Court refuses to rule on the status of the human embryo in vitro by pointing out that “there is no need here to examine the delicate and controversial issue of the beginning of human life as art. 2 of the Convention is not put into question in this case”³⁹. The Court has only stated that, given the economic and patrimonial scope of this article, human embryos cannot be reduced to the status of goods. Referring exclusively to the economic and patrimonial scope of art. 1 of Protocol No. 1 to the Convention, the reasoning of the Court is deficient. The embryo cannot be included in the category of goods because it cannot be left out of a relationship with the human species, making impossible “the failure to recognize his humanity”⁴⁰. Or, the purpose of the principle of human dignity is to distinguish the human person from animals or goods.

Clarifications regarding the meaning of the concept of “human embryo” are also brought by the Court of Justice of the European Union (hereinafter referred to as CJEU) through two reference decisions in the case *Brüsle*⁴¹ and in the case *International Stem Cell Corporation*⁴², which may have a major influence on the status of the human embryo in national and European law. Furthermore, we shall briefly consider the two decisions.

Mr Oliver Brüsle was the holder of a German patent on human neuronal precursor cells obtained from human embryonic stem cells and the process of their production. In 2004, the Bundespatentgericht (Federal Patent Court) cancelled his patent at the request of Greenpeace eV, a decision which the defendant appealed before Bundesgerichtshof (Federal Court of Justice). The referring court decided to request the Court in Luxembourg to pronounce a preliminary decision on the interpretation of the provisions of Art. 6 par. (2) let. (c) of the Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions, which provides that “(...) are not considered patentable: (...) (c) the use of human embryos for industrial or commercial purposes”. In other words, it was questioned whether the exclusion from patentability of the human embryo concerned all stages of life from the fertilization of the egg or whether it was allowed before a certain stage of development. Three preliminary questions have been asked. The decision given by the CJEU in this case is very important because, by the first question, it was asked to give a definition to the human embryo. In the Court's view, this is an autonomous notion of Union law, and a uniform definition must be given to the human embryo throughout the EU territory. In connection with the context and the objective of the Directive, the Court considered that the notion of “human embryo” must be broadly interpreted. In this regard, it pointed out that any human ovum must be considered a “human embryo” from the moment it is initiated the process of development of a human being, regardless whether it is triggered by fertilization or by any other artificial technique. The Court in Luxembourg did not accept “having a materialistic and arbitrary interpretation of the embryo according to which the fertilized egg would not have the status of an embryo until reaching a certain stage of development, for example, after implantation in the fallopian tube”⁴³ and in response to the first question it stated that it “constitutes a “human embryo”

³⁹ §215.

⁴⁰ M. Herzog-Evans, cited work, p. 68.

⁴¹ European Court of Justice (Grand Chamber), *Oliver Brüstle v Greenpeace eV.*, Judgment of 18 October 2011. Reference for a preliminary ruling: Bundesgerichtshof – Germany, Case C-34/10. European Court Reports of Cases 2011 I-09821.

⁴² European Court of Justice (Grand Chamber), *International Stem Cell Corporation v Comptroller General of Patents, Designs and Trade Marks*, Judgment of 18 December 2014. Request for a preliminary ruling from the High Court of Justice (England & Wales), Chancery Division (Patents Court), Case C-364/13.

⁴³ G. Puppink, *Synthetic analysis of the E.C.J. Case C-34/10 Oliver Brüstle v. Greenpeace Ev. and its ethical consequences*. (Can be consulted at the address https://c-fam.org/turtle_bay/synthetic-analysis-of-the-ecj-case-c-3410-oliver-brustle-v-greenpeace-e-v-and-its-ethical-consequences/). For a comment of this decision, see as

within the meaning of Art. 6 par. (2) let. (c) of the Directive any human egg even from the time of fertilization, any unfertilised human ovum in which was implanted the nucleus of a mature human cell and any unfertilised human ovum which, by parthenogenesis, has been stimulated to divide and develop⁴⁴. By the second question it was tried to clarify whether the exclusion from patentability of the use of human embryos for industrial or commercial purposes also concerned their use for scientific research purposes. The Court stated that the subject-matter of a patent application⁴⁵ cannot be distinguished from the rights granted by the patent⁴⁶, and therefore they have been excluded from patentability as well. The Court considered that "Only the use for therapeutic or diagnostic purposes which applies to the human embryo and is useful to it may be the subject of a patent"⁴⁷. With regard to the third question asked to the Court, it was raised the issue of patentability of an invention in the case where the invention does not directly concern the use of human embryos, but a product obtained by the previous destruction of human embryos or a process requiring a starting material previously obtained by destroying human embryos. The CJEU ruled out that such an invention should be considered as being unpatentable. In other words, we cannot separate the patent claims from the previous destruction of human embryos.

International Stem Cell Corporation (ISCO) filed two patent applications before the Intellectual Property Office in the United Kingdom. These applications involved the activation by parthenogenesis of unfertilised human ova, considered human embryos in Brüsle case, a reason why the application for patent registration was rejected. The referring court asked the Court in Luxembourg to determine whether the judgment in Brüsle case is correct because "according to current scientific knowledge (...), human partenotes, it would have been demonstrated that they develop only until the blastocyst stage, within approximately five days"⁴⁸, but they are not capable of triggering the development process that leads to a human being. The process involves activating the ovocyte, in the absence of sperm cells, using chemical and electrical techniques. Unlike a fertilized egg, a partenote does not contain paternal DNA, which is necessary for the development of extraembryonic tissue. The CJEU refuses to rule out on whether the partenote are "human embryos" and therefore it does not exclude their patentability, but leaves it to national courts to decide whether "they have or not the intrinsic ability to evolve into a human being"⁴⁹. The importance of the decision is to give green light to the patenting of research involving alternative methods of obtaining embryonic stem cells, but a possible negative effect could be the "patent tourism"⁵⁰.

The European Citizens' Initiative (ECI) represents an instrument of participatory democracy that was launched in April 2012. By this instrument, EU citizens can collect one million signatures from at least a quarter of the Member States in order to ask the European Commission to act in a certain field. "One of Us" is one of these European citizens' initiatives launched for ensuring the protection of human beings at the moment of conception in the areas of competence of EU⁵¹. The EU was requested to stop financing activities which

well A. Pele and R. Asis Roig, *Entre raison et tradition: dignité humaine et identité européenne*, Romanian Journal of Comparative Law nr. 2/2012, pp. 9-26.

⁴⁴ §38.

⁴⁵ Residing in the use of human embryos for scientific research purposes.

⁴⁶ In principle, industrial and commercial uses.

⁴⁷ §46.

⁴⁸ §17.

⁴⁹ §36.

⁵⁰ For further developments, G. Belova, A. Hristova, *Some problems related to the "human embryo" in the European Union Law*, International Conference Knowledge – Based Organization, Vol. XXII, no. 2/2016, p. 295.

⁵¹ For details, see <https://oneofus.eu/about-us/>.

involve the destruction of human embryos, the fields concerned being particularly: research, development aid and public health. The organizers of the initiative presented their requests firstly to the representatives of the European Commission on 9 April 2014⁵², and the following day they attended a hearing in the European Parliament. The arguments brought forward by the organizers included as well the decision of the CJEU in *Brüsle* case, but, as well noted, it covered Directive 98/44/EC on the legal protection of biotechnological inventions and did not regulate the use of human embryos in the context of scientific research, and therefore it did not address the question whether such research could be carried on and whether they can be funded. The Commission decided not to put forward a legislative proposal as it considered that the current funding framework was a appropriate⁵³.

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⁵²http://europa.eu/rapid/press-release_STATEMENT-14-115_en.htm .

⁵³According to Mrs. Máire Geoghegan-Quinn, the European Commissioner for Research, Innovation and Science: "We have examined this citizens' initiative and granted all due attention. However, the Member States and the European Parliament have agreed to continue to fund research in this area in a justified manner. Embryonic stem cells have unique characteristics and they could be at the origin of life-saving treatments, which is already being studied in certain clinical trials. The Commission will continue to apply EU-funded research the strict rules and ethic restrictions already in force, including the fact that we will not finance the destruction of embryos".