

SOME PROBLEMS RELATED TO THE “HUMAN EMBRYO” IN THE EUROPEAN UNION LAW

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Abstract: *The following article is dedicated to the topic of human dignity - the human embryos and the legal framework they are regulated by in the EU: The Charter of Fundamental Rights of European Union and the EU Court practice. For the purpose, the authors look first and foremost at the EU Directive 98/44, regulating the legal protection of biotechnological inventions which aim at balancing the human beings' dignity and integrity with the need to preserve the social function of patents as a vector for the competitiveness of the European biotech industry. Two key EU Court cases are analyzed, both of which reflecting the evolution of the Court of Justice on the European Union's Case Law on Stem Cell Patents, namely Case C-34/10 Oliver Brüstle v Greenpeace e. V. and Case C-364/13 International Stem Cell Corporation. The article looks then at the European Citizens' Initiative “One of us”, which aims at securing Juridical protection of the dignity, the right to life, as well as to the integrity of every human being from conception in those areas of EU competence where such protection has a particular importance.*

Keywords: human dignity, human embryo, stem cell patents, EU Court practice

Introduction

The concepts of human dignity and the person's right to integrity are among the key underlining principles outlined in the Charter of Fundamental Rights of European Union. In its' capacity of a prime value of the European Union foundation, human dignity is stipulated as inviolable [1], whilst the person's right to integrity, outlined in Article 3 of The Charter of Fundamental Rights of European Union, and interpreted in the context of medicine and biology calls for:

- The free and informed consent of the person concerned, according to the procedures laid down by law,
- The prohibition of eugenic practices, in particular those aiming at the selection of persons,
- The prohibition on making the

human body and its parts as such a source of financial gain,

- The prohibition of the reproductive cloning of human beings. [2]

The above two EU prime values are closely related to yet another topic that features wide juridical and public discussion, namely the human embryos. The patentability of human embryonic stem cells in Europe has turned into a matter of heated discussions at EU regulatory, judicial and public forums.

EU Directive 98/44/EC on the Legal Protection of Biotechnological Inventions

- The juridical context of the human embryo and its patenting is a subject matter covered by the EU Directive 98/44/EC on the Legal Protection of Biotechnological Inventions. [3] The

Directive's main goal is to provide a fruitful environment for research across the EU by encouraging investment and balancing out the differences between the laws and practices of Member States regarding the biotech industry.

The EU Directive 98/44/EC does take into account the ethical considerations deriving from its' subject matter and further distinguishes between patentable and unpatentable matters. Inventions which are proven new and result from an inventive step are patentable (such as biological material isolated from its natural environment). Contrary to that, the human body, throughout the various stages of its development, is deemed unpatentable by the Directive. Article 6 of the Directive states that any invention whose commercial use would be contrary to *ordre public* shall not be patentable: "uses of human embryos for industrial or commercial purposes." [4]

The Directive text's interpretation by the EU court practice, however has proven to be a difficult matter, as evident by the below two cornerstone court cases:

- Court Case I: European Court of Justice Case C-34/10 Oliver Brüstle v Greenpeace e.V.[5]

- The case gained large publicity due to the milestone decision the European Court of Justice ruled, marking a leap forward in legal recognition of the dignity of the human embryo. [6]

- The ruling of the Court sets forth a moral agenda that permeates not just EU patent law, but notions of morality and ethics at a worldwide level.

- In 1997, Dr. Oliver Brüstle successfully applied for a patent regarding the isolation and production of neural precursor cells, as extracted from embryonic stem cells originating from Israel, In 2004, the Greenpeace group filed a suit challenging the validity of the patent, claiming that the stem cells extracted by Dr. Brüstle originated from human embryos, thus his patent request was contrasting to

the *ordre public* as stipulated in the EU Directive 98/44/EC. [7]

- The technologies subject to the patent request raised by Dr. Brüstle held significant promise for treating neurological disorders such as Parkinson's diseases and Alzheimer's syndrome, mainly through the transplantation of neural cells into the nervous system. However, moral and ethical concerns were raised, as to the process by which this treatment was normally conducted. For the neural precursor cells to be acquired, they had to be extracted from the cerebral tissue of human embryos - a process that destroys the embryo as a whole. Nevertheless, Dr. Brüstle introduced a new approach, as the technology that he patented allowed for the extraction of such cells from pluripotent embryonic stem cells.

- Greenpeace challenged the patent in question before the German Federal Patent Court, which ruled that the patent was invalid regarding the use of precursor cells obtained from human embryonic stem cells and the processes used to obtain them, according to national German law.

- This determination was appealed by Dr. Brüstle before the German Federal Court of Justice, which in turn applied for a preliminary reference before the European Court of Justice. [8]

- Brustle's view was that the Directive had not defined what an embryo is. He believed that an "embryo" comes into being 14 days after fertilisation. Since his embryonic stem cells were taken from five or six day old embryos, they could not be banned by the Directive.

- The court, however, supported and declared that "any human ovum must, as soon as fertilised, be regarded as a "human embryo" if that fertilisation is such as to commence the process of development of a human being. [9]

- For the judges, the question was whether the exclusion from patentability of the human embryo concerned all stages of life starting from the fertilisation of the

ovule or whether it was possible to allow patentability in certain circumstances, for example, before a certain stage of development.

Three questions were raised before the Court, all seeking greater clarity regarding the interpretation of the Biotech Directive.

The first question was seeking better clarification of the meaning of the “human embryo” as stated in Article 6 of the Biotech Directive. The Court noted the importance of settling a uniform definition of a legal term when Member States have not been delegated the responsibility to do so, which is the case here. Finding a standard definition to this, however, proved complicated, as the moral implications of the issue appear conflicting with the fact that Member States have different opinions as to when life begins.

The Court claimed that the “human embryo” starts at the moment a human ovum is fertilized, as they believed this marked the commencement of the process of developing into a human being.

The Advocate General’s observation on this landmark case needs to be noted and analyzed: In his assessment, he tackles the question when the *human body* begins to develop, as he claims it is the human body that demands respect and protection. Further, he states that science can give us an understanding of the biological processes surrounding human conception, but it cannot tell us “when the human person truly begins.” [10] The latter statement is largely seen as challenging the Scientific Society’s position on the topic.

The second question before the Court was aiming to better understand the meaning of “uses of human embryos for industrial or commercial purposes,” and determine whether an exception exists when it comes to scientific research. Here the Court stated that a grant of patent is clearly demonstrative of an industrial or commercial intent, and that despite any scientific research purposes, the subject

matter of a patent cannot be separated from the rights a patent confers. However, the Court did not seem to give a satisfying argument as to why this must be, and the Advocate General only offers the contention that a grant of patent inherently implies the mass production of stem cells, and thus the destruction of large numbers of embryos. [11]

The third question before the Court questioned the patentability of an invention in the cases where the invention does not directly utilize human embryos, but involves material obtained by the prior destruction of human embryos. The Court decided that an invention must be ruled as non-patentable if any of the necessary steps regarding its implementation result in the destruction of human embryos, or if the invention is used in the destruction of future embryos. This latter came as a natural continuation of the line of thought applied in the first two questions. Such ruling out prevented a loophole that could potentially allow applicants evasion of the terms of patentability through creative wording in the patent application.

Such judgment of the Court closely followed the preliminary opinion of Advocate General Bot, who elaborated on the case: Bot concluded that patentability and research are not intertwined concepts, and a negation of one would not foreclose the other. [12]

In summary, the Brüstle decision is marked in the history of human embryo as one creating a roadblock for significant scientific progress, by placing a higher value on perceived notions of collective morality in sacrifice of the objective scientific good. [13]

Court Case II: Case C-364/13 International Stem Cell Corporation

The case at hand, and more specifically the EU Court ruling is contrasting to its previous ruling in the Brüstle Case analyzed in the above lines, where the Court decided that an ovum

would only constitute a 'human embryo' if it were 'capable of commencing the process of development of a human being'. The Court hence justified the unpatentability of both fertilised ova and non-fertilised ova on the basis that the latter were, just like embryos created by fertilisation of an ovum, 'capable of commencing the process of development of a human being'. [14]

In the present case, International Stem Cell Corporation applies for patent registration in the UK the process of 'parthenogenetic activation of oocytes for the production of human embryonic stem cells'. The process entails the activation of a human ovum by chemical and electrical techniques. Such an activated ovum can reach the blastocyst phase, however it is unable to develop further, as it lacks the paternal DNA necessary to form extra-embryonic material. The process falls into the third category of processes which Brüstle deemed unpatentable by virtue of constituting a 'human embryo'. [15]

The Deputy Judge of the High Court, questioned whether the Court's ruling in Brüstle Case is correct if, as per current scientific knowledge, parthenotes are unable to develop into a human being. In his judgment, he implied that the Court should rule in favour of excluding this particular process from the notion of 'human embryo'. The Deputy Judge observes that:

Stem cells have the potential to revolutionise the treatment of human disease because of their capacity to differentiate into almost any type of adult cell. The recitals to the Biotech Directive express two competing policy considerations. On the one hand, the research in the field of biotechnology is to be encouraged by means of the patent system, and on the other hand, that patent law must be applied so as to respect the fundamental principles safeguarding the dignity and integrity of the person...The Biotech Directive is to be interpreted in a

way that balances these competing policy considerations. [16]

The Court states that an unfertilised human ovum which further development has been stimulated by a parthenote, must have the 'inherent capacity of developing into a human being'. The Court further emphasizes that the question deciding the ruling is whether the parthenote can develop into a human being, and not whether it can commence this process. The decision whether a parthenote has such a capacity is left for the national courts to determine.

The change of reasoning as evident by the Court's ruling remains unexplained. It becomes clear, however, that while in the present case the information provided suggested that parthenotes could not develop into human beings, the information in Brüstle suggested that parthenotes could develop into human beings. The Court did not deal with the eventuality that the parthenote could be genetically manipulated in such a way that it can develop to term as International Stem Cell Corporation had amended their applications for registration to exclude the prospect of additional genetic information. [17]

In summary, the Court's decision qualifies Brüstle so that parthenotes are not automatically included in the definition of 'human embryo' and thus excluded from patenting. In this way, it allows for the patenting of biological research involving alternative methods of obtaining embryonic stem cells. The Court's decision further raises two points of consideration:

First, it allows for Member States to ban patentability of parthenotes under Article 6(1) of the Directive on the basis of public order or morality. As the patentability of parthenotes thus becomes dependent on Member States' discretion, a 'patent tourism' could emerge, whereby parthenote stem cell researchers will locate in jurisdictions which welcome their processes and avoid those which do not. [18]

Second, the ruling does not explicitly state at what point the organism develops into a human being and is thus excluded from the ‘human embryo’ concept. The Court leaves it to the national courts to determine whether the parthenote has the ‘inherent capacity to develop into a human being’. This leaves the decision with the national courts to decide if the parthenote has the inherent capacity to develop into a human being, and if not, whether it is prohibited from being patented on grounds of morality and/or public order. This leaves the decision power to the national courts, whilst depriving the EU of a common principle to guide them in the ruling of this common subject.

In summary, patenting parthenotes is no longer definitively prohibited due to their definition as ‘human embryos’ under Brüstle. Their patentability becomes a subject of the Member States’ interpretation, be it on the grounds of public order or morality, or potential classification as ‘human embryos’ in light of the new definition.

In addition to the juridical and political implications deriving from the prime values rooted in the very establishment of the EU: human dignity and the right to integrity, the public reaction to the issues arising from the Brüstle Case and the International Stem Cell Corporation Case escalated in the formation of a new procedure, called the European Citizens’ Initiative (ECI).

European Citizens’ Initiative ‘One of Us’

The ECI is a recent instrument of participative democracy, dating back to April 2012. It provides EU citizens with the right to organize and collect one million signatures from at least seven Member States and ask the EU Institutions to take action in a certain field. “One of Us” was the third such initiative to be launched in the EU. Its’ purpose is directed at halting all EU funds for any activities which involve the destruction of the human embryo. [19]

The “One of Us“ Initiative has greater political potential than any other initiative that has been undertaken so far to protect the dignity of the person and life from conception at a European scale. [20] The desired outcome of the initiative is a concrete ban of life-destroying policies in the EU budget, as well as a political change and greater awareness of the need to respect the wish of at least one million European citizens. The initiative therefore aims to affect two major areas of work:

- Research that destroys human embryos or uses human embryonic stem cells
- Development aid that could be used to directly or indirectly finance abortion. [21]

The organizers presented their requests to the European Commission, followed by a hearing from the European Parliament on April 10, 2014. The Brüstle judgement of the European Court of Justice was referred to by the organisers while presenting their arguments. However, the Court noted in that ruling which concerned the Biotech Directive (98/44/EC), that the purpose of the European legislation in question is not to regulate the use of human embryos in the context of scientific research; the ruling was limited to the patentability of biotechnological inventions and did not deal with the question of whether such research can be carried out and whether it can be funded. The request of the One of Us Initiative was hence declined by the Commission, which concluded that the existing budget framework is appropriate and shall not be amended. The reasons behind the rejection of the initiators’ request were elaborated by Máire Geoghegan-Quinn, European Commissioner for Research, Innovation and Science, said: "We have engaged with this Citizens' Initiative and given its request all due attention. However, Member States and the European Parliament agreed to continue funding research in this area for a reason. Embryonic stem cells are unique and offer

the potential for life-saving treatments, with clinical trials already underway. The Commission will continue to apply the strict ethical rules and restrictions in place for EU-funded research, including that we will not fund the destruction of embryos.” [22]

Conclusion

The multi-aspect concepts of human dignity and the person’s right to integrity feature a wide and growing importance in the EU.

The gravity of the human, political,

judicial and R&D implications behind the human embryo is indeed evident, and clearly evolving in time. [23]

Starting with the Brüstle case and the EU Court’s ruling, through the ‘new’ interpretation as understood in the International Stem Cell Corporation, escalating in the formation of the people’s “One of Us” Initiative, the topic of the human embryo remains actual in the public and juridical forums, yet with time, new accents and wider contexts are being attached to it.

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