



## EUROPE'S LANDMARK DECISION ON STEM CELL PATENTS, OR: THE STRICT EUROPEAN VIEW ON LIFE

In a landmark decision on October 18, 2011, the highest court of the European Union—the Court of Justice—decided on the patentability of stem-cell-related inventions (case number C-34/10). The dispute arose around the definition of the term “human embryo” in the European Biotechnology Directive. Based upon this decision, the Court will now apply a very broad definition, which will result in nonpatentability and invalidity of many stem-cell-related inventions in Europe. The impact on biotechnology and life sciences innovator companies will be significant.

### INTRODUCTION

The patentability of inventions on “life” has long been subject of a heated debate. Over time, European patent laws have been amended to clarify that the use of human embryos for industrial and commercial purposes shall not be patentable. However, the definition of the term “human embryo” remained unclear. In particular, questions arose as to whether and to what

extent human stem cells are covered by the term as well, and how inventions merely using human stem cells shall be treated with respect to patentability.

In its landmark decision, the Court of Justice has applied a broad definition to the term “human embryo.”

According to the Court, the definition shall include the fertilized human ovum. Reaching even further, the term shall also include artificial cell types including the ones obtained by cell nucleus transfer from a mature human cell into a nonfertilized human ovum. This technology was used to obtain the clone sheep “Dolly,” for instance.

The Court of Justice further ruled that not only is any such—broadly defined—human embryo unpatentable, but also that every invention that requires the prior destruction of a human embryo shall not be the subject of a patent. This also applies to inventions

using stem cell lines that resulted from the destruction of a human embryo long before the cell line was employed for the invention.

This ruling will have a major impact on companies dealing with the development of biomedical products and therapies based on embryonic stem cells. It might also affect companies working with cells not derived from the human embryo, but with a developmental potential close to that of embryonic stem cells.

## THE FACTS OF THE UNDERLYING CASE

In December 1997, the neurobiologist Prof. Oliver Brüstle filed a patent application with the German Patent and Trademark Office, and subsequently a patent was granted (DE 197 56 864.5). The claims of the patent are directed to isolated and purified precursor cells derived from embryonic stem cells with the potential to develop into neuronal cells to be used to cure severe diseases like Parkinson's.

With the intention to prevent life from commercialization, Greenpeace e.V. opposed Mr. Brüstle's patent. The German Federal Patent Court ("GFPC"), concerned with the respective nullity suit, declared Mr. Brüstle's patent invalid insofar as it related to procedures allowing precursor cells to be obtained from human embryonic stem cells. The GFPC came to the conclusion that in this regard, the patent violated Section 2(2) item 3 of the German Patent Act ("GPA"), which stipulates that the use of human embryos for industrial or commercial purposes is contrary to *ordre public* and morality and thus shall be unpatentable.

Section 2 GPA finds its basis in Art. 6 of the European Biotechnology Directive 98/44/EC (the "Directive"). Since the interpretation of the German provision also required interpretation of the underlying Directive, the German Federal Court of Justice ("GFCJ"), to which Mr. Brüstle had appealed, decided to stay proceedings and referred three main questions to the Court of Justice in order to obtain a ruling on the proper interpretation of the Directive that ensures unified application of the Directive in all EU member states.

## THE RULING OF THE COURT OF JUSTICE

First, the Court of Justice was asked to interpret the term "human embryo," since the Directive does not contain any definition thereof. In its decision, the Court of Justice largely followed the foregoing opinion of the advocate general, applying a broad interpretation of the term "human embryo." In particular, the Court decided that any human ovum after fertilization, any nonfertilized human ovum into which the cell nucleus from a mature human cell has been transplanted, and any nonfertilized human ovum whose division and further development have been stimulated by parthenogenesis constitute a "human embryo."

According to the Court of Justice's interpretation, a "human embryo" is to be assumed at "day one" of fertilization and even includes artificial cell types, which have not been fertilized at all. In this regard, the Court considered it as decisive that the respective cell is capable of commencing the process of development of a human being, and this capability already exists from the moment of fertilization.

With regard to stem cells obtained from a human embryo at the blastocyst stage (as in Mr. Brüstle's patent), the GFCJ decided 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."

For the second question posed by the GFCJ, the Court had to examine whether the concept of "uses of human embryos for industrial or commercial purposes" as set out in Art. 6(2) (c) of the Directive also covers the use of human embryos for purposes of scientific research. In this regard, the Court outlined that the use of human embryos for scientific research purposes is also a form of industrial and commercial application and, therefore, falls under the exclusion from patentability. However, the Court found that the intention of the Directive was not to exclude the use of a human embryo for industrial or commercial purposes where it concerns the use for therapeutic or diagnostic purposes that are applied to the human embryo itself and that are useful to it, for example to correct a malformation and improve the chances of life.

Finally, the Court of Justice dealt with the third question posed by the GFCJ: whether an invention is unpatentable even if the use of human embryos does not form part of the claimed invention, but where such use is a prerequisite for practicing the invention. Continuing to apply a strict ruling, the Court of Justice decided that even if the claims of a patent do not recite the use of human embryos, as long as the implementation of the invention requires the destruction of human embryos, a patent shall not be granted.

The fact that an invention can be based on cells that have been obtained through the destruction of a human embryo at a stage long before the invention was actually made (as in the case of the Brüstle patent) was considered irrelevant. The mere fact that the invention required an embryo to be destroyed was considered by the Court of Justice as sufficient to deny patentability.

## RESULTING CONSEQUENCES FOR STEM CELL PATENTS AND PATENT APPLICATIONS

**Binding for EU Member States.** The ruling of the Court of Justice is binding for the member states of the European Union. As a result, national stem-cell-related patent applications in the member states of the European Union that fulfill the above-mentioned criteria will be refused, and already granted patents may be revoked as expected for the Brüstle patent when the German Federal Supreme Court applies these criteria.

**Nonbinding for the EPO and Non-EU Member States.** Interesting follow-up questions arise from the fact that the Court of Justice's decision is not binding for the European Patent Organization ("EPO") itself, since it is a supranational organization and not formally part of the EU. It is binding only for the member states of the European Union. Notably, not all member states of the European Patent Convention ("EPC") are members of the European Union (for example, Switzerland, Norway, and Serbia). Thus, the consequences of the judgment do not automatically apply to all states for which a European patent can be sought.

However, even though not immediately and formally bound by the Court of Justice's decision, it is anticipated that the EPO examiners will follow the ruling laid down by the Court of Justice, with effect for all countries for which patents can be applied under the EPC. The introduction of the corresponding provision to the EPC, *i.e.*, Rule 28(2)(c) EPC, was done with the intent to align the EPC rules with the Biotechnology Directive 98/44/EC.

Moreover, the EPO already had come to similar conclusions in its Enlarged Board of Appeal decision G 2/06, in which the board had to decide at least in part on comparable questions. In G 2/06, the EPO decided that claims directed to products that, as described in the application, at the filing date could be prepared exclusively by a method necessarily involving the destruction of the human embryos from which the said products are derived, even if that method is not part of the claims, shall not be allowable. The Court of Justice's decision could thus be seen as complementing and further developing tendencies for which foundations had already been laid by EPO case law.

**Another Incentive for a Unified Patent System in Europe.** The Court of Justice's decision also underlines that the patent system in Europe is not yet fully harmonized. In its decision G 2/06, the Enlarged Board of Appeal on the one hand confirmed that the EPO has no possibility to refer legal questions to the Court of Justice of the European Union, but on the other hand, it based its ruling on the interpretation of the European Directive, which is the Court of Justice's primary task to ensure a unified application of European Directives throughout Europe.

This incongruent situation again demonstrates the advantages that a unitary European patent system would offer, including a European patent court and the possibility to refer legal questions to the Court of Justice. This is of particular importance, as exemplified by the above-referenced case wherein the Court of Justice could have decided contrary to the EPO. This would have led to the awkward situation of two different interpretations of similar legal provisions within the European territory. To prevent such situations in

the future, a unified European patent system would be desirable.

**Severe Difficulties are Foreseeable in Practical Application of the Ruling.** On the scientific side, it follows from the decision that two restrictive criteria will have to be met for stem cell patents and patent applications. First, the claimed invention shall not be directed to a human embryo, which appears to be broadly defined in the Court of Justice decision by the capability of the respective cell type to commence the process of development of a human being. Second, an invention is excluded from patentability where the technical teaching that is the subject matter of the patent application requires the prior destruction of human embryos.

Several follow-up questions could be likely to arise in the practical application of these criteria. For example, how should an invention be treated that is directed to cells (or their use), wherein the cells were obtained from the human embryo at a multi-cell stage without actually killing the embryo?

The Court of Justice came to the conclusion that for the technical teaching of the Brüstle patent, where stem cells are taken from the human embryo at the blastocyst stage, the embryos necessarily have to be destroyed. However, new technologies (developed after the filing date of the Brüstle patent) might allow obtaining and propagating cells from the human embryo without actually killing the embryo. Unfortunately, the Court of Justice (and also the EPO in G 2/06) did not address this issue in detail. However, for applications employing such "life-sustaining" technologies, patentability should come down to the question whether the derived cells are capable of commencing the process of development of a human being. This core question was not decided by the Court of Justice but was left for the national courts to decide. Hence, the question whether a cell derived from a human embryo that was not killed in obtaining the cell can commence the process of development of a human

being, *i.e.*, is a totipotent cell, has to be decided on a case-by-case basis by a national authority.

Even if a patent application relates to stem cells obtained from sources other than the human embryo, a similar reasoning may be applied: As the Court of Justice has laid down a very broad interpretation of the human embryo, including artificial cell types, each totipotent cell, even if not derived from the human embryo, appears to be excluded from patentability as it falls under the broad definition of the Court of Justice. Again, according to the Court of Justice the question whether a stem cell is in fact totipotent shall be decided by a national court.

The fact finding and evidence will lead to difficulties; ultimately, this would require experimental proof that a claimed stem cell in fact develops into a human being. Thus, it may eventually be the burden of the applicant to demonstrate that the claimed cells are not totipotent, but only pluripotent, *i.e.*, only have the capability to develop into a limited number of cell types and not into a complete human being. It remains open how such evidence may be conclusively collected without again compromising the fundamental principles relating to human life upon which the Court of Justice's decision is based.

**Practical Advice for Stem Cell Patent Applicants.** As stem cell research in general aims to obtain cells that have the capability to develop into as many different cell types as possible, the differentiation between a totipotent cell, *i.e.*, a human embryo according to the Court of Justice definition, and a pluripotent cell might become difficult. For instance, continued progress of genetic reprogramming of cells to more and more pluripotent cells in the case of the so-called induced pluripotent stem cells (iPSCs) might result in totipotent cells capable of commencing the process of development of a human being. Also in these instances, national courts would have to decide about the developmental

potential of the claimed cells, and in case of doubts, the burden of proof that the claimed cells do not fall under the definition of a human embryo would be with the applicant.

Thus, it is advisable when drafting a patent application concerning human stem cells to include statements and maybe even experimental data showing that the cells involved in the invention are not capable of commencing the process of development of a human being.

In this regard, care should be taken when drafting an inventive step argument based on an “increased totipotency” as a beneficial effect. This line of argument might bring the claimed cells into or at least close to the definition of the human embryo and thus toward unpatentable subject matter.

For inventions based on stem cells that can also be obtained from the human embryo without ultimately destroying the embryo, it might be problematic that the “life-sustaining” production method is not displayed by the generated cells, as they are most likely not distinguishable from cells obtained by a method that requires destruction of the embryo. However, a patent might still be obtained when the “life-sustaining” production method is included in the claims or at least in the specification.

## LAWYER CONTACTS

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