

SEED

MONEY



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The European Court of Justice is soon to determine a case that examines whether inventions resulting from the use of human embryonic stem cell lines may be patentable in Europe. The case could have major ramifications for the commercial funding of embryonic stem cell research in Europe. Fiona Duffy peers into her

Notwithstanding this, there is no specific legislation governing stem cell research in Ireland, nor is there any regulation. The Irish Stem Cell Foundation, in its policy document published in April 2010, states that the lack of a regulatory regime creates confusion and could potentially allow improper research to take place.

The legal position of the embryo in Ireland was considered in the case of *Roche v Roche*. The Supreme Court – while holding that the embryo, *in vitro*, has moral status and, in the words of the Chief Justice, “cannot be divorced from our concepts of human dignity” – held that the embryo, *in vitro*, is not “the unborn” within the meaning of article 40.3.3 of the Constitution, and therefore is not constitutionally protected under that provision.

The Irish Medical Council, in the seventh edition of its *Guide to Professional Conduct and Ethics for Registered Medical*

Practitioners, no longer contains the provision that all fertilised ova created through IVF must be used for normal implantation and must not be deliberately destroyed. This means that there is no guidance to doctors on what should become of surplus embryos.

Science Foundation Ireland (SFI) notes on its website

that “pending legislation from the Department of Health and Children governing assisted human reproduction and related practices, and in line with a

current directive from the Department of Enterprise, Trade and Innovation, SFI is not in a position to fund research using human embryonic stem cells”.

The definition of ‘human embryo’ is shortly due to be considered by the Grand Chamber of the European Court of Justice (ECJ) in the case of *Oliver Brüstle v Greenpeace eV*. On 10 March 2011, Advocate General Yves Bot, an advisor to the ECJ, delivered his opinion. Generally, the court tends not to overturn the opinion of the advocate general.

This case comes before the ECJ by way of reference from the Federal Court of Justice in Germany for preliminary ruling on the meaning of ‘human embryos’ in article 6(2)(C) of Directive 98/44/EC,

“In effect, this directive prohibits the granting of a patent for a biotechnological invention, the commercial exploitation of which would be contrary to public order or morality”



specifically asking whether it includes all stages of the development of human life, including unfertilised human ova and stem cells obtained from human embryos at the blastocyst stage (see 'Greenpeace action' panel, p31).

The court is also required to consider the concept of "uses of human embryos for industrial or commercial purposes", within the meaning of article 6(2)(c) of the directive.

Mother of invention

Directive 98/44/EC was transposed into Irish law by SI 247 of 2000, the *European Communities (Legal Protection of Biotechnological Inventions) Regulations 2000*. Section 6(1) of the directive and the Irish transposing legislation provides: "A patent shall not be granted in respect of a biotechnological invention, the commercial exploitation of which would be contrary to public order or morality, provided that the exploitation shall not be deemed to

be so contrary only because it is prohibited by law."

The directive and SI at section 6(2) specifically provides: "Any of the following in particular shall not be regarded as a patentable invention on the basis of paragraph (1):

a) A process of cloning human beings,

b) A process of modifying the germ line genetic identity of human beings,

c) The use of human embryos for industrial or commercial purposes,

d) A process of modifying the genetic identity of animals which is likely to cause them suffering without any substantial medical benefit to man or animal, and animals resulting from such a process."

In effect, this directive prohibits the granting of a patent for a biotechnological invention, the commercial exploitation of which would be contrary to public order or morality, and specifically "the use of human embryos for industrial or commercial purposes" shall not be regarded as a patentable invention.

This prohibition, however, does not affect inventions for therapeutic or diagnostic purposes that are applied to the human embryo, and are useful to it (recital 42 of the preamble to the directive).

It is interesting that, despite the fact that it was open to all member states to express their views, only two member states availed of the opportunity. These states took the view that the definition of 'human embryo' should be left to the sole discretion of each member state.

FACTS

- > The legal position of the embryo in Ireland was considered in *Roche v Roche*. The Supreme Court, while holding that the embryo, *in vitro*, has moral status that "cannot be divorced from our concepts of human dignity", held that such embryos are not "the unborn" within the meaning of article 40.3.3 of the Constitution. Therefore, they are not constitutionally protected under that provision
- > The definition of 'human embryo' is shortly due to be considered by the Grand Chamber of the European Court of Justice (ECJ) in the case of *Oliver Brüstle v Greenpeace eV*
- > This case comes before the ECJ for preliminary ruling on the meaning of 'human embryos' in article 6(2)(C) of Directive 98/44/EC. It specifically asks whether the human embryo includes all stages of the development of human life, including unfertilised human ova and stem cells obtained from human embryos at the blastocyst stage
- > The court is also required to consider the concept of "uses of human embryos for industrial or commercial purposes" within the meaning of article 6(2)(c) of Directive 98/44/EC
- > In effect, this directive prohibits the granting of a patent for a biotechnological invention, the commercial exploitation of which would be contrary to public order or morality and, specifically, "the use of human embryos for industrial or commercial purposes" shall not be regarded as a patentable invention

GREENPEACE ACTION – BACKGROUND

Mr Brüstle has a German patent, which was granted in 1997, concerning isolated and purified neural precursor cells, processes for their production from embryonic stem cells, and the use of neural precursor cells for the treatment of neural defects.

It is claimed, in the patent specification, that the transplantation of brain cells into the nervous system allows the treatment of numerous neurological diseases, for example, Parkinson's. The process used is to transplant immature precursor cells, which exist only during the brain's development phase.

The proceedings in Germany arose out of an action by Greenpeace to have the patent annulled. Greenpeace is against the commercial exploitation of human embryos and suggests that the only reason why Mr Brüstle would want to patent his invention is for commercial purposes. It argued that, as the invention is derived from human embryonic stem cells, it is unpatentable under the directive.

In considering the definition of the term 'human embryo' within the meaning of article 6(2)(3) of Directive 98/44/EC, Advocate General Bot considered the legislation of different member states, the provisions of the directive itself, and current scientific information.

From his analysis of the legislation, it was clear that member states were not all in agreement with each other. Principally, they fell into two categories, namely:

- Those where the human embryo exists from fertilisation, and
- Those where the human embryo exists when

the fertilised ovum has been transferred into the lining of the womb.

Noting the provisions of article 5(1) of the directive and, in particular, the reference to the human body "at various stages of its formation and development" and the requirement to respect the fundamental primacy, dignity and integrity of the person, he took the view that the definition of 'human embryo' should be by reference to the development of the human body.

Finally, he commented that contemporary science cannot tell us when the human person truly begins. Indeed, he suggests that the question – when life begins – can only be answered in the negative, because it is impossible to detect the appearance of life.

He took the view that totipotent cells (see *glossary*) represent the first stage of the human body, as each of them has the capacity to develop into a complete human being, and, on that basis, they should be legally categorised as embryos.

He then noted that the blastocyst is the product of the capacity of the totipotent cells to develop into a human body, and, as such, categorised the blastocyst as an embryo for the purposes of this directive.

In relation to pluripotent cells, he noted that, as they cannot develop separately into a complete human being, they cannot be defined as an embryo within the meaning of the directive. He noted that, as embryonic stem cells taken in isolation are no longer capable of developing into a complete individual, they

cannot be categorised as human embryos within the meaning of the directive.

Notwithstanding this, he stated that it is not possible to ignore the origin of a pluripotent cell. He noted that it is not a problem, in itself, that it comes from some stage in the development of the human body – provided only that its removal does not result in the destruction of that human body at the stage of its development at which the removal is carried out.

In the particular case he was dealing with, it was noted that, if the pluripotent stem cell was removed from the blastocyst (in itself an embryo), such removal would result in the destruction of the developing human body. In the circumstances, he took the view that inventions relating to pluripotent stem cells can be patentable only if they are not obtained to the detriment of an embryo, whether through its destruction or its modification.

He therefore held that:

- 1) Article 6.2(c) of the directive must be interpreted to the effect that the concept of 'human embryo' applies from the fertilisation stage to the initial totipotent cells, and to the entire ensuing process of the development and formation of the human body, including the blastocyst,
- 2) Pluripotent embryonic stem cells are not included in the concept of a human embryo because they do not, in themselves, have the capacity to develop into a human being, and
- 3) An invention must be excluded from patentability if it has resulted from the prior destruction of human embryos.

The advocate general noted that 98/44/EC is a harmonising directive and that, as such, the definition of 'human embryo' within the meaning of the directive must be defined specifically for European union law and that such definition be applicable in all member states. He did differentiate and note that, while each member state is free to authorise research under conditions laid down by that state, the patenting laws for such products in Europe must all be governed by the same laws.

He also emphasised that this definition is for the purposes of the directive only.

It would now seem that inventions resulting

from the use of human embryonic stem cell lines derived from 'spare' human embryos left over from IVF treatment, and which would otherwise be destroyed, may not be patentable in Europe. That is not to say that research on embryos and human embryonic stem cell lines cannot be carried out.

One wonders, however, whether funding for such research will be available to researchers and universities if the resultant inventions cannot be patented. If upheld by the Grand Chamber, this decision could have serious financial and economic repercussions for such research in Europe.

As against the financial question, there are always the moral and ethical questions, and the stance of Greenpeace is that the human body should not be exploited for commercial gain. ■

LOOK IT UP

Cases:

- *Oliver Brüstle v Greenpeace eV* (case no C34/10)
- *Roche v Roche & ors* [2009] IESC 82

Legislation:

- Directive 98/44/EC
- *European Communities (Legal Protection of Biotechnological Inventions) Regulations 2000* (SI 247 of 2000)

Literature:

- Medical Council, *Guide to Professional Conduct and Ethics for Registered Medical Practitioners* (2009)

GLOSSARY

- **Blastocyst** – an embryo that has developed to the point of having two different cell components and a fluid cavity. In other words, it has started to differentiate.
- **Pluripotent stem cells** – the stem cells present in very early embryos, called embryonic stem

cells, are pluripotent. They cannot grow into a whole new body, but in the right environment, they can grow into almost any of the body's cell types.

- **Totipotent cells** – a newly fertilised egg is totipotent because it has the potential to form an entire body.