The Protection of Stem Cell Inventions in South Africa

Stem cell research is on the increase as researchers realise the potential of stem cells for the development of possible therapies for treatment of a wide range of human illnesses and diseases which are currently difficult or impossible to treat.

There are a number of different kinds of stems cells, but they all have one aspect in common, the ability to develop into more than one form of human tissue.

Embryonic stem cells are derived from an embryo at the pre-implantation stage of development.

Totipotent stem cells are early embryo cells that can develop into all the different types of cells required to develop into a fully functioning human being.

Pluripotent stem cells, including embryonic stem cells, are able to develop into most human tissues, but are not capable of developing into a human being. There are pluripotent stem cells in the adult body as well, but they are not able to develop into as broad a range of cells as embryonic stem cells. For example, there are bone marrow cells that can develop into blood cells as well as liver or cardiac cells, and neural stem cells that can give rise to neurones and glial cells, but can also develop into heart, lung or liver cells.

Multipotent cells are those that only give rise to a limited number of human tissues.

Embryonic stem cell research is controversial, in that it may involve destruction of the embryo which is perceived by some as contrary to morality.

Legislation relating to stem cells in South Africa

The National Health Act 61 of 2004, which was intended to cover stem cells was assented to in July 2004, but chapter 8, which deals with the "Control of Use of Blood, Blood Products, Tissue and Gametes in Humans", has not yet been promulgated. Moreover, the regulations drafted to give substantive meat to the provisions of Chapter 8 have not been well received by researchers, and may be significantly revised. Stem cell use in South Africa is therefore currently governed by the Human Tissue Act 65 of 1983.

The Human Tissue Act requires that written consent by the donor(s) be given for the removal or withdrawal of tissue (unless it is tissue which is replaceable by natural processes, in which case consent may be oral). In addition, tissue may only be withdrawn for medical or dental purposes, subject to certain restrictions. One restriction which pertains to stem cells is that placenta, foetal tissue and umbilical cord tissue may only be withdrawn with the consent of the Minister of Health and is subject to any conditions mentioned in the consent.

The Human Tissue Act provides that no person except an authorised institution may receive any payment for the supply of any tissue for or to another person. The Human Tissue Act also precludes the genetic manipulation of gametes of zygotes outside the human body.

Patentability of inventions relating to stem cells

The South African Patents Act 57 of 1978 does not preclude patenting of stem cells per se. However it is possible that, in particular, embryonic stem cell inventions may fall within the provisions of section 25(4) or section 36 of this Act.

Section 25(4) provides that *"a patent shall not be granted for an invention the publication or exploitation of which would be generally expected to encourage offensive or immoral behaviour…"*

Section 36(1) provides that *"if in the case of any application it appears to the Registrar… that the use of the invention to which the application relates would be generally expected to encourage offensive or immoral behaviour, he shall refuse the application."*

Furthermore, section 36(2) provides that *"If it appears to the Registrar that any invention in respect of which an application for a patent is made might be used in any manner contrary to law, he may refuse the application…".*

In South Africa, as there is no substantive examination of a patent application, it is questionable whether the Registrar will ever refuse an application on this ground. However it remains open to the Registrar to refuse an application on the basis that it would generally be expected to encourage offensive or immoral behaviour.

Furthermore, in South Africa a patent can be revoked on the grounds either that the invention concerned is not patentable under section 25, or that the application for the patent should have been refused in terms of section 36. Thus, even if a patent is granted on an invention which would be generally expected to encourage offensive or immoral behaviour, or which might be used in a manner contrary to law, it can later be revoked on this ground.

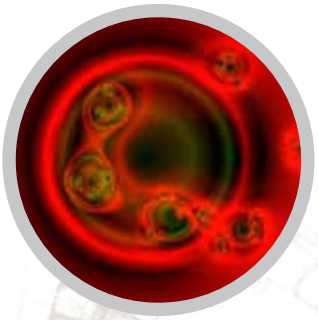
These sections all turn on a question of morality and whether the embryonic stem cell invention would generally be considered to be immoral, either by the Registrar or by the courts.

Our courts have not yet had to deal with this issue, but it is probable that they will consider foreign guidelines when making any decision. The final result may be somewhere between the more restrictive approach that is followed in many countries in Europe and the fairly lenient approach that is followed in the USA.

In Europe, the European Patent Office (EPO) has objected to the patenting of human embryonic stem cells and methods of isolating them. The patent application in question was European patent application EP9690321.1 and the European Examining Division refused the application on the basis that such subject matter is excluded from patentability in terms of Article 53(a) and Rule 23d (now Rule 28(c)) of the European Patent Convention (EPC).

Article 53 provides that no patent shall be granted in respect of *"(a) inventions the publication or exploitation of which would be contrary to "ordre public" or morality…".*

Rule 28(c) provides that no patent shall be granted in respect of biotechnological inventions which, in particular, concern uses of human embryos for industrial or commercial purposes.



The applicant appealed the decision, but the Enlarged Board of Appeal (G02/06) confirmed the rejection *inter alia* on the basis that since the term "embryo" is not defined either in the EPC or the EU Biotech Directive (98/44/EC), which is to be used as a supplementary means of interpretation of the EPC, the exclusion applies to any embryo and therefore cannot be restricted to an embryo of a certain age as was suggested by the applicant.

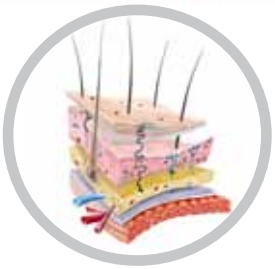
This decision is more restrictive than legislation in some member states of the EPC. For example, in the UK the Intellectual Patent Office (IPO) has issued guidelines on the patentability of human embryonic stem cells that provide that processes or methods of obtaining stem cells from human totipotent cells are not patentable, and neither are processes of obtaining stem cells from human embryos. This is in keeping with the Rules of the EPC and the EU Biotech Directive. However, a distinction is made between an embryo and a pre-embryo based on findings of the Warnock Report (a report of the Committee of Inquiry into Human Fertilisation and Embryology), which formed the basis for the UK Human Fertilisation and Embryology Act 1990.

This report sets the deadline for transition from pre-embryo to embryo at 14 days, as this is considered to be a significant stage of development with the advent of the primitive streak, which is a visible longitudinal axis of bilateral symmetry around which all embryonic structures organize and align during the early stages of avian, reptilian and mammalian embryonic development. Therefore, the pre-embryo is patentable in terms of UK law.

It may be argued that the Enlarged Board of Appeal objection in terms of Article 53 specifically relates to the patenting of human embryonic stem cells where it is necessary to destroy the human embryo in order to obtain the stem cells, as these were the facts before the EPO in the case above. As technology has now developed so that it is not necessary to destroy the human embryo, it is possible that an objection on the basis of lack of morality would not apply to methods involving this new technology. In the UK, for example, it is possible to obtain a patent for inventions involving human pluripotent cells, with the proviso that the cells cannot be derived through destruction of the human embryo.

In the USA, although patenting of "human beings" is prohibited, the United States Patent and Trademark Office (USPTO) has no fundamental policy objection against the patenting of human embryonic stem cells as long as the usual requirements for patentability are met (including novelty, inventiveness and utility). One of the first embryonic stem cells patents granted was for US patent 5,843,780 (corresponding to EP patent application EP9690321.1, which was objected to by the EPO as discussed above).

Recently, the USPTO has upheld this patent and two others which were challenged on the basis of obviousness in re-examination proceedings. Furthermore, the restrictions on federal funding for embryonic stem cell research that were part of the Bush policy in the USA have now been lifted by President Obama. It is possible that this may encourage more research on embryonic stem cells in the USA, with the resultant filing of a higher frequency of embryonic stem cell patents in the US.



Conclusion

As discussed above, there is currently no legislation that prohibits patenting inventions pertaining to stem cells *per se* in South Africa as long as the other requirements of patentability are met. One of these requirements is that the invention must not be "immoral". South African law (in terms of the Human Tissue Act) sanctions certain aspects of stem cell research, such as that placental, foetal and umbilical cord tissue may be withdrawn from a person if the Minister of Health has consented and the prescribed conditions of the consent are followed.

The National Health Act contains a similar provision with embryonic tissue and stem cells additionally specified in the list of tissues. It could therefore be argued that at least these aspects are not considered "immoral" by South African society.

On the other hand, those aspects of stem cell research which are prohibited by law, such as reproductive cloning of a human being, can be argued to be "immoral" and thus not patentable.

It is also important to remember that the granting of a patent does not provide the patentee with the right to perform any act with respect to the invention. Thus, even if a patent is granted, a patentee may be prevented from putting its invention into practice by other South African laws, such as the Human Tissue Act.

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