

Human embryo and stem cell patenting

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Biotechnology Directive (98/44/EC)

■ Article 6

- “1. *Inventions shall be considered unpatentable where their commercial exploitation would be contrary to ordre public or morality; however, exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation.*
2. *On the basis of paragraph 1, the following, in particular, shall be considered unpatentable: [...]*
 - (c) *uses of **human embryos** for industrial or commercial purposes;”*

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European Patent Convention

■ Art 53(a) – EPC

“European patents shall not be granted in respect of:

(a) inventions the commercial exploitation of which would be contrary to “ordre public” or morality; such exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States;”

■ Rule 28(c) – Implementing Regulations

“Under Article 53(a), European patents shall not be granted in respect of biotechnological inventions which, in particular, concern the following: [...]

*(c) uses of **human embryos** for industrial or commercial purposes;”*

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What is a ‘human embryo’?

■ EPC

- *WARF (G2/06)*

■ Biotechnology Directive

- *Brüstle (C-34/10)*

- *International Stem Cell Corporation (C-364/13)*

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Stem cells can be obtained from developing embryos

Characteristics

- Self-renewal
- Differentiation

Classification

- **Totipotent** -- all cell types + whole organism
- **Pluripotent** -- all cell types + not whole organism
- **Multipotent** -- particular cell types only

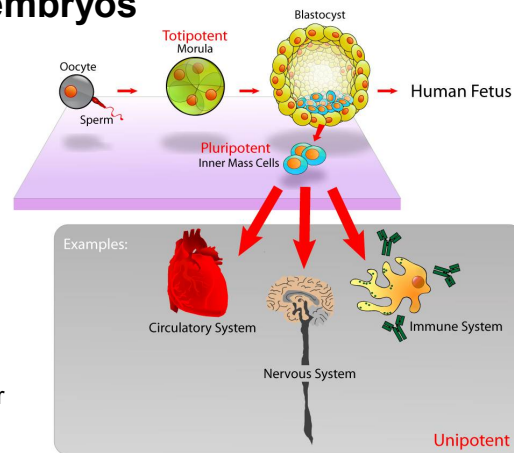


Diagram by Mike Jones

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EPC – G2/06 - WARF

- Decision of EPO Enlarged Board (Nov 2008)

“Rule 28(c) EPC (formerly Rule 23d(c) EPC) forbids the patenting of claims directed to products which - as described in the application - at the filing date could be prepared exclusively by a method which necessarily involved the destruction of the human embryos from which the said products are derived, even if the said method is not part of the claims.”

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Biotech Directive – Brüstle (C-34/10)

- Decision of CJEU (18 October 2011)
- Court decided that “human embryo” includes:
 - i. Fertilised human ovum
 - ii. Non-fertilised human ovum + transplanted adult cell nucleus
 - iii. Non-fertilised human ovum stimulated to divide by parthenogenesis
- Reason: “*capable of commencing the process of development of a human being*”

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Biotech Directive – Brüstle (C-34/10)

- Exclusion applies:
 - where patent requires “*the prior destruction of human embryos or their use as base material*”
 - ‘*even if the description of the technical teaching claimed does not refer to the use of human embryos.*”
- Exclusion does not apply to:
 - “*use for therapeutic or diagnostic purposes which is applied to the human embryo and is useful to it*”

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Biotech Directive – ISCC (C-364/13)

- Decision of CJEU (18 December 2014)

“... an unfertilised human ovum whose division and further development have been stimulated by parthenogenesis does not constitute a ‘human embryo’, within the meaning of that provision, if, in the light of current scientific knowledge, it does not, in itself, have the inherent capacity of developing into a human being, this being a matter for the national court to determine.”

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Summary

- **Patentable**
 - Human stem cells not obtained from embryos
 - Use of embryos for therapies or diagnostics that are useful to the embryo
 - Unfertilised human ova stimulated to divide by parthenogenesis - providing that *it does not, in itself, have the inherent capacity of developing into a human being.*
- **Not patentable**
 - Inventions requiring the destruction of human embryos

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Post-/SCC UK IPO Guidance (25 March 2015)

- Inventions requiring the destruction of human embryos - NO
- Human stem cells not derived from human embryos - OK
- Inventions for therapeutic or diagnostic purposes - OK
- **Processes for obtaining stem cells from human embryos - NO**
- **Human totipotent stem cells - NO (Art 5(1))**



[See more information about this Statutory guidance](#)

Statutory guidance

Inventions involving human embryonic stem cells: 25 March 2015

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Contents

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This notice replaces and updates the guidance given in the Office's previous Practice Notices dated 3 February 2009¹, 17 May 2012², and 27 June 2014.

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Thank you!

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