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;”
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;”

What is a ‘human embryo’?

- EPC
  - WARF (G2/06)

- Biotechnology Directive
  - Brüstle (C-34/10)
  - International Stem Cell Corporation (C-364/13)
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

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.”
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”

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”
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.”

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
Post-ISCC 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))

Thank you!

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