Patentability of human embryonic stem cells

The UK perspective

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Patentability requirements

• Novel
• Involves an inventive step
• Capable of industrial application
• Not excluded matter
Section 1(3) 1977 Patents Act

“A patent shall not be granted for an invention the commercial exploitation of which would be contrary to public policy or morality”
Paragraph 3, Schedule A2

The following are not patentable inventions:

a. The human body, at various stages of its formation and development
b. Processes for cloning human beings
c. Processes for modifying the germ line genetic identity of human beings
d. Uses of human embryos for industrial or commercial purposes
Considerations

1. Are pluripotent hESCs contrary to public policy or morality in the UK?

2. Are hESCs *per se* excluded from patentability under the Act as they are the product of an excluded method?
Public policy/morality (1)

- Human embryo research generally not considered to be unethical
  (Source: MORI poll commissioned by HFEA, 2005)

- Not all research on human embryos should be prohibited in the context of the law and social attitudes
  (Source: House of Lords Select Committee on Stem Cell Research)

- Human Fertilisation and Embryology (Research Purposes) Regulations
Considerations

1. Are pluripotent hESCs contrary to public policy or morality in the UK?

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The following are not patentable inventions:

d. Uses of human embryos for industrial or commercial purposes
Directive 98/44 EC
“The Biotech Directive”

• Implementation in 3 phases
  – **Articles 1-11** by the Patents Regulations 2000 (28 July 2000)
  – **Articles 13 & 14** by The Patents (Amendment) Rules 2001 (6 July 2001)
  – **Article 12** by The Patents and Plant Variety Rights (Compulsory Licensing) Regulations 2002 (1 March 2002)
The Biotech Directive: Interpretation

- Articles
- Recitals
Exclusions: Relevant Articles

Art 5(1): The human body, at various stages of its formation and development...cannot constitute a patentable invention

Art 6(2): The following shall be considered to be unpatentable
(a) processes for cloning human beings
(b) processes for modifying the germ line genetic identity of human beings
(c) uses of human embryos for industrial or commercial purposes
Exclusions:
The Recitals

(38) …processes to produce chimeras from germ cells or totipotent cells of humans and animals are obviously excluded from patentability…..

(40) …interventions in the human germ line and the cloning of human beings offends against *ordre public* and morality…..

(42) …uses of human embryos for industrial or commercial purposes must also be excluded from patentability…..
Patentable inventions: The Articles

- **Art 5(2):** An element isolated from the human body or otherwise produced by means of a technical process….may constitute a patentable invention, even if the structure of that element is identical to that of a natural element
Patentable inventions: The Recitals

(17)...research aimed at obtaining and isolating [elements from the human body] valuable to medicinal production should be encouraged by means of the patent system

(18) ..since the patent system provides insufficient incentive for encouraging research into and production of biotechnological medicines needed to combat rare or ‘orphan’ diseases, the Community and Member states have a duty to respond adequately to this problem
Summary

1. On balance, pluripotent hESCs are not considered to be contrary to public policy and morality in the UK

2. hESCs *per se* are not considered to be excluded from patentability under the Act
Scope of protection

“The claim or claims shall define the matter for which the applicant seeks protection”

Section 14(5)(a) 1977 Patents Act
(Article 84 EPC)
Scope of claims (1)

“A cell culture comprising human embryonic stem cells which are capable of proliferating *in vitro* for over one year, and maintain the potential to differentiate to derivatives of endoderm, mesoderm and ectoderm tissues”
Scope of claims (2)

• Cells are difficult to define

• Product-by-process claims

• Establishment of cell lines
Human Stem Cells
NON-PATENTABLE:

• Human totipotent cells
  – “The following are not patentable inventions:
    (a) the human body, at various stages of its formation
    and development…” Article 5(1)

• Methods of isolating human embryonic stem cells
  – uses of human embryos for industrial or commercial
    purposes Article 6(2)(c)
Human Stem Cells
PATENTABLE:

• Human pluripotent stem cells
• Human adult stem cells
  – multipotent, unipotent, progenitor cells

• Scope of claims important
For Information about UK Practice

- UK Examination Guidelines for Biotechnological Inventions available at:
  http://www.ipo.gov.uk/biotech.pdf

- UK Patent Office Practice Notice, April 2003