



Biotech and Pharmaceutical Patents - special problems

Module 2A
Master of European Intellectual Property Law
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Special Problems

- Invention/Discovery (art. 52, R.27 EPC, art. 3 BD)
- Exceptions to Patentability:
 - Contrary to ordre public/morality (art. 53(a), R.28 EPC, art. 6 BD)
 - Plant varieties, animal varieties, essentially biological processes for the production of plants or animals (but not microbiological processes) (art. 53(b), R.26, 27 EPC, art. 4, 2 BD)
 - Methods for treatment, diagnostic methods (art. 53(c) EPC)
 - The human body in its natural state (R.29 EPC, art. 5 BD)

Special Problems

- The patentability criteria (art. 54-56 EPC, art. 3.1 BD)
 - Novelty:
 - Second medical use (art. 54(4) and (5) EPC)
 - Selection inventions
 - Inventive Step.
 - Industrial application:
 - Gene sequences (R. 29(3) EPC, art. 5.3 BD, EPO guidelines)

Special Problems

- Sufficiency of disclosure (Art. 83 EPC).
- Supplementary patent protection.
- Data exclusivity.
- Patent infringement
 - Experimental use defence.
 - Equivalence.

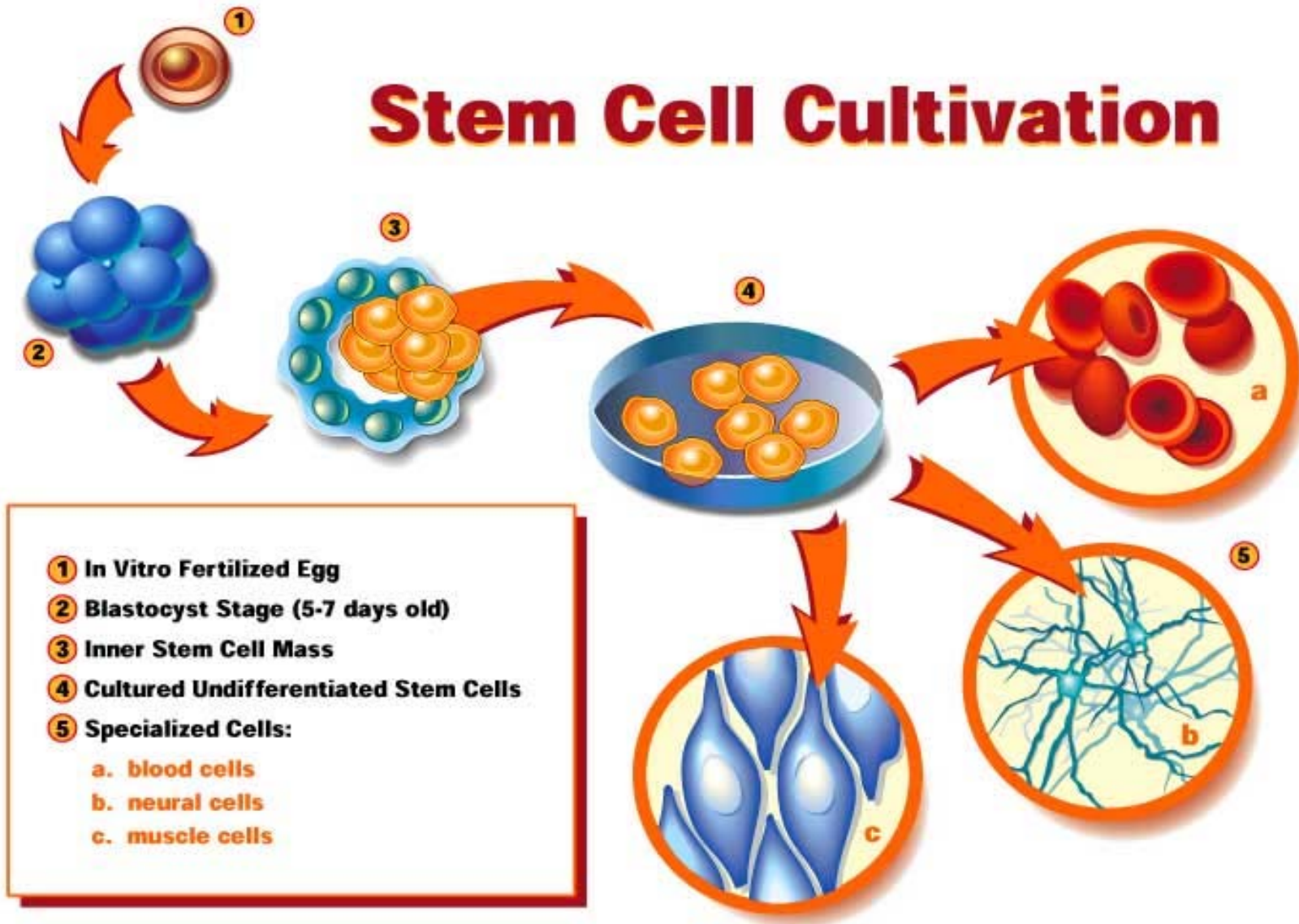
The morality exclusion (Art. 53(a) EPC)

- 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
- See T 19/90, T 356/93

The exemplifying list (R.28 EPC)

- Under Article 53(a), European patents shall not be granted in respect of biotechnological inventions which, in particular, concern the following:
 - (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;
 - (d) processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes

Stem Cell Cultivation



Harvesting embryonic stem cells

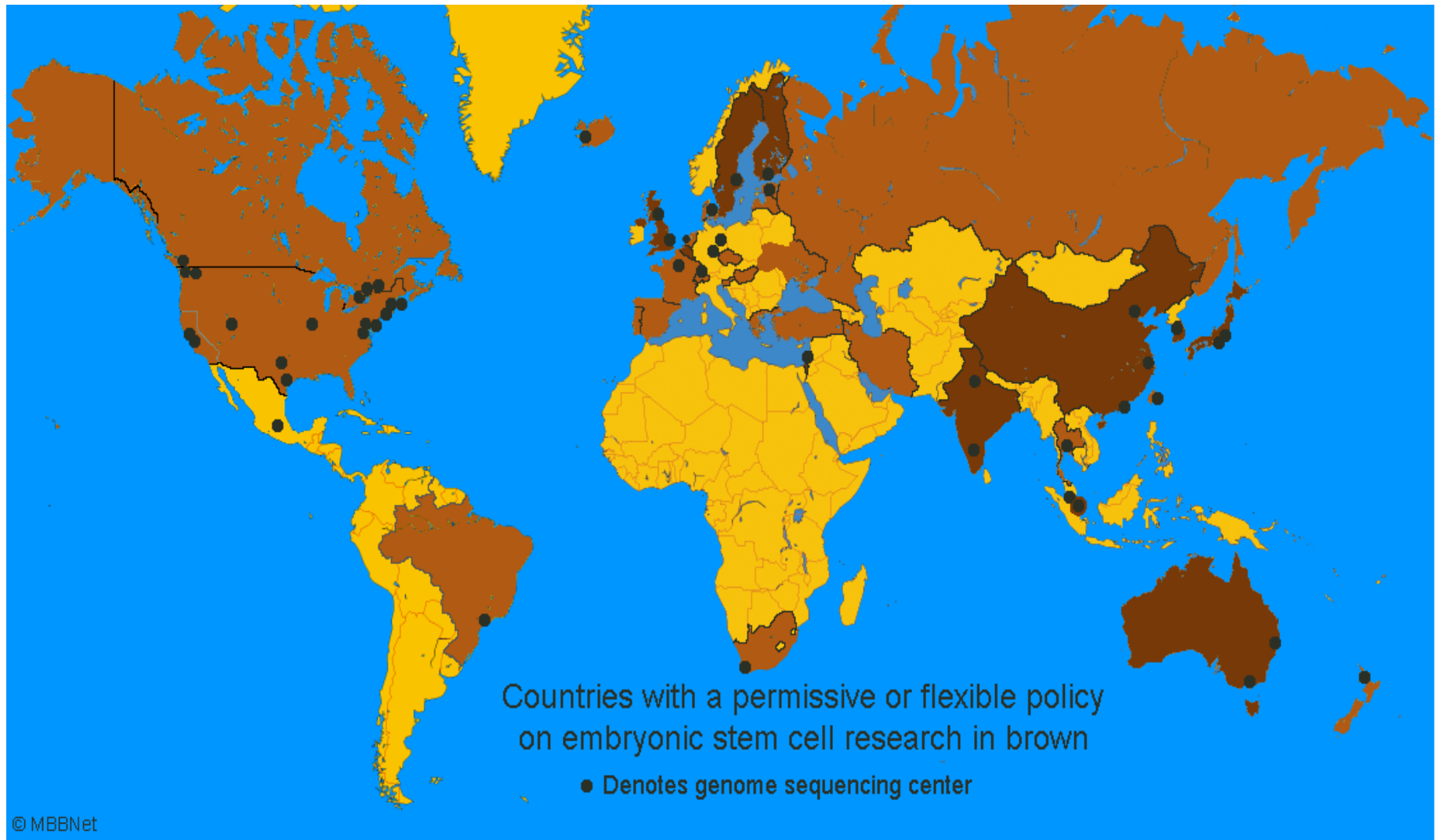


Stem Cells

- Unspecialized cells, renewable through cell division
- Aimed at specialization
- Different kinds
 - Embryonic
 - Fetal
 - Adult
- With different potential
 - Totipotent
 - Pluripotent
 - Multipotent

Human Embryonic Stem Cell (hESC) Research

- Drug/toxicity testing, differentiating into different cell types for cell therapy etc.
- James A. Thomson 1998 (WARF) – first hESC line.
- Characteristics of hESC research:
 - Difficult to establish hESC lines.
 - 400 cell lines worldwide (2007)
 - Advanced methods.
 - Ethical and regulatory issues.



hESC Patents

- Patents with direct claims to hESC (cells as such, culturing methods, methods of differentiation)
 - EPO: 0 (2009)
 - No patents on inventions requiring destruction of embryos (Decision of the Enlarged Board of Appeal, G 2/06, WARF)
 - UK: 100 grants, 500 applications (2009)
 - Sweden: 3 (2009)
 - US: 41 grants (2006)
 - The WARF/Geron monopoly (Thomson's breakthrough technology, 3 broad patents (under re-examination by USPTO)).

hESC Patentability

- Europe
 - Interpretation of Art. 53(a) and R.28 EPC (the morality clause)
 - Interpretation of R.28(c) EPC (uses of human embryos for industrial or commercial purposes)
 - Different national approaches
 - EPO G 2/06 restrictive interpretation (destruction of embryos)
 - ECJ referral C-34/10

hESC patentability

- USA
 - No moral exclusion
 - The issue has been broad patents
 - Thomson patents, 3 broad patents
 - Licensing agreements
 - USPTO reexamination

Effects of G 2/06 (WARF)

- The human body in its natural state, including elements, is non-patentable (R.29(1) EPC)
 - Precludes patents on human embryos and totipotent cells as such.
- The uses of human embryos for industrial or commercial purposes is not patentable (R.28(c) EPC)
 - Precludes patents on an invention consisting of a hESC cell culture which was made from human embryos that are destroyed in the process.

ECJ Referral (C-34/10)

- Oliver Brüstle v. Greenpeace et al. (German Federal Supreme Court)
- 1. Human embryo definition
- “2. What is meant by the expression 'uses of human embryos for industrial or commercial purposes'? Does it include any commercial exploitation within the meaning of Article 6(1) of the Directive, especially use for the purposes of scientific research?”

ECJ Referral (C-34/10)

- “3. Is technical teaching to be considered unpatentable pursuant to Article 6(2)(c) of the Directive even if the use of human embryos does not form part of the technical teaching claimed with the patent, but is a necessary precondition for the application of that teaching,
 - (a) because the patent concerns a product whose production necessitates the prior destruction of human embryos,
 - (b) or because the patent concerns a process for which such a product is needed as base material?”

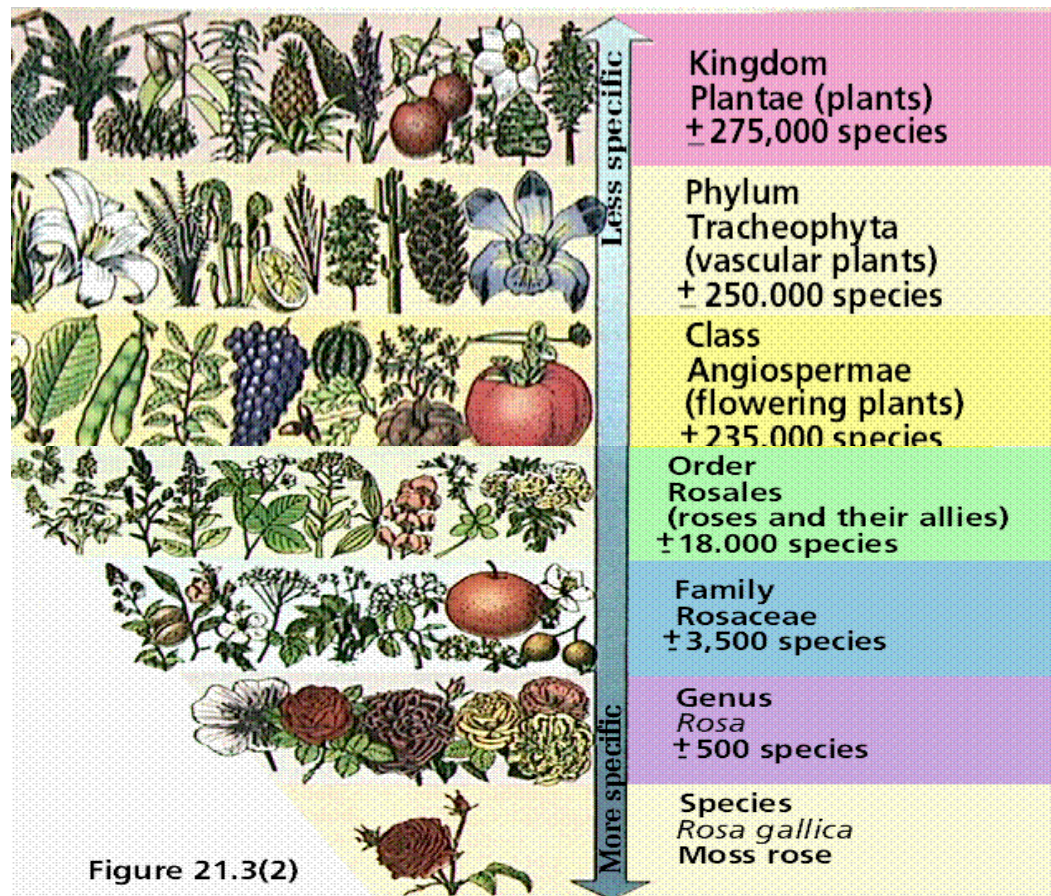
Remaining questions

- Uses of hESC or -derived products
- ECJ decision
- National courts

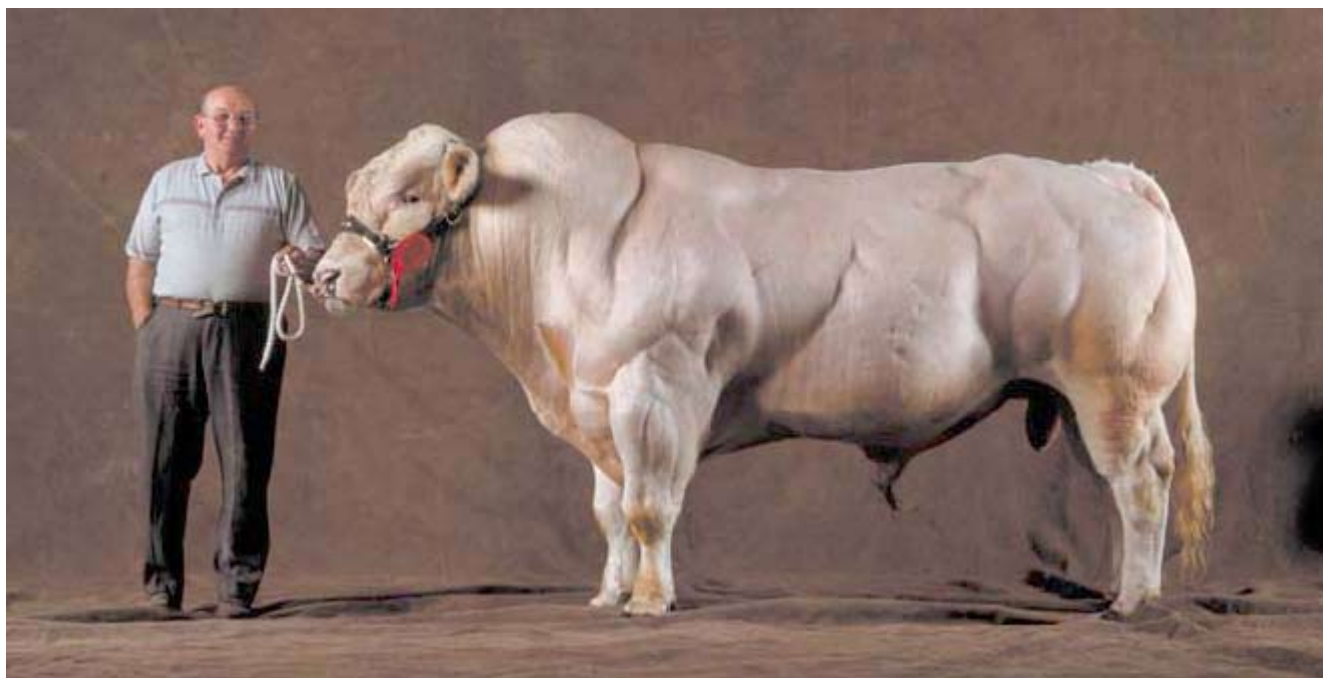
Animals and Plants

- Exclusion for plant or animal varieties or essentially biological processes for the production of plants and animals (Art. 53(b) EPC)
- Microbiological processes and products are patentable
- However, plants and animals are also patentable if the technical feasibility of the invention is not confined to a particular plant or animal variety (R.27(b) EPC)
- See G 1/98 (Novartis) and T 356/03 (PGS)
- See T 315/03 and T 19/90 (Harvard Oncomouse)

Classification System

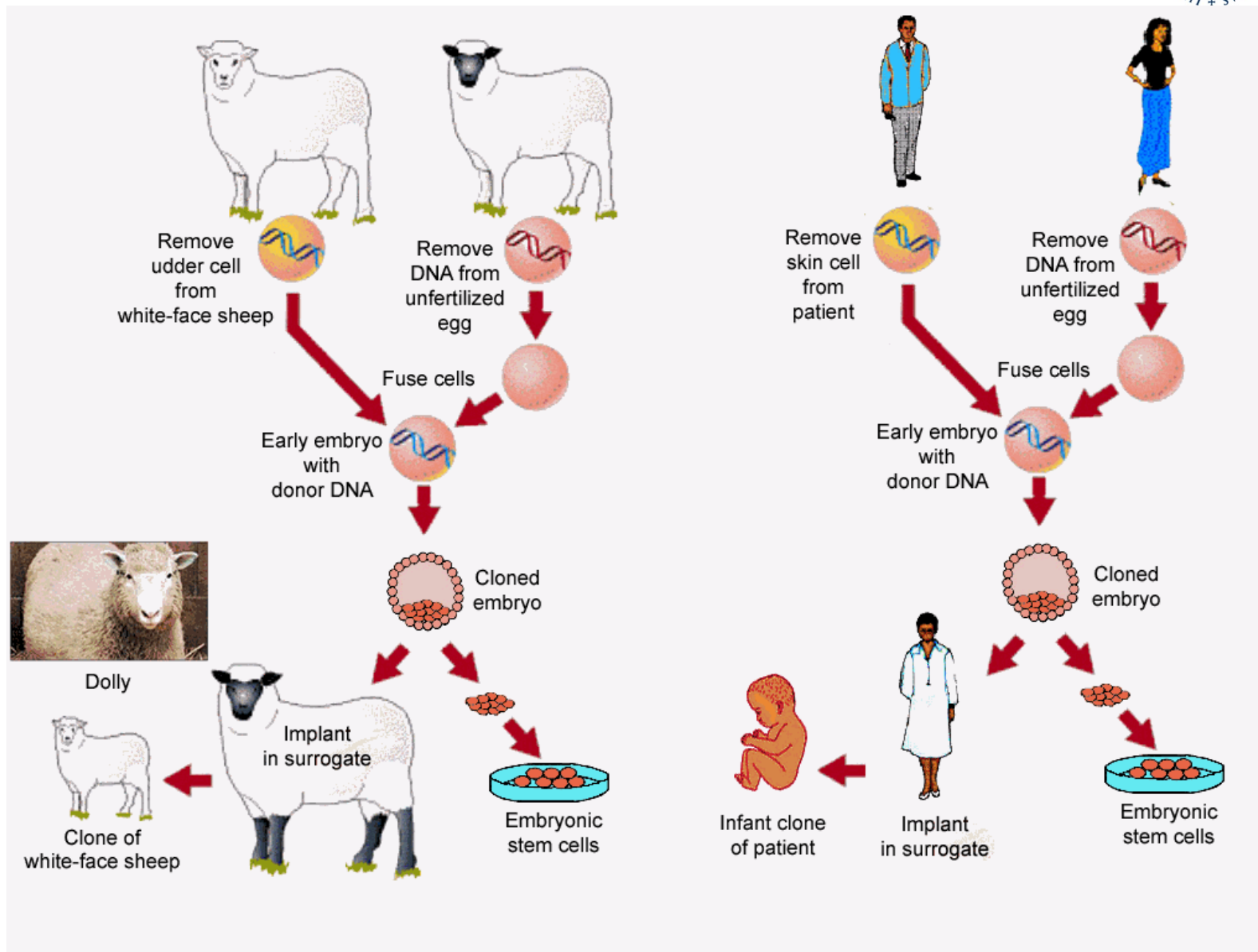


Belgian Blue – a genetically modified animal?



Cloning





Questions

- Can I get a patent on:
 - 1) A cloned sheep (eg. Dolly)
 - 2) The DNA extracted from an animal skin cell?
 - 3) The cloned animal stem cells?
 - 4) The process of cloning the sheep?
 - 5) A cloned human being?
 - 6) The DNA extracted from a human skin cell ?
 - 7) The cloned human stem cells?
 - 8) The process of cloning the human?

Selection Inventions

- Novelty of specific subject-matter already subject to a generic disclosure?
- *“A generic disclosure does not usually take away the novelty of any specific example falling within the terms of that disclosure, but that a specific disclosure does take away the novelty of a generic claim embracing that disclosure.”* (Guidelines for examination in the EPO)
- Ex. Copper-metal

Selection Inventions

- Better but similar effect
- Quantitative relation - the narrower the selection is in relation to the generic term, the more likelihood there is of the selection being deemed new

Novelty of a Specific Chemical Compound

- A generic disclosure does not usually take away the novelty of a specific embodiment
- A specific disclosure take away the novelty of a generic claim embracing that disclosure
- See e.g. T 181/82, T 7/86 (single substituent selected from a generically defined group)

Novelty of a Generic Chemical Formula

- Same principles as for specific compounds if a smaller group of compounds is selected from a wider generic formula (Markush)
- Problems when a generic formula overlaps a generic prior art disclosure
- T 81/85 (Use of disclaimers)
- T 12/90 (disclaiming the total overlapping area)

Novelty of Ranges (intervals)

- The selected range has to be narrower than the known range
- The selected range should be sufficiently far removed from any specifically disclosed values, e.g. the end-points of the known broad range, or pre-published examples within the known range
- The selected range should not be arbitrarily chosen but should result in a better technical effect (“purposive selection”) See T 279/89

Novelty of Therapeutic Effects

- Second medical uses...
- A general indication is not novelty destroying for a more exactly defined treatment result.

Experimental use exemption

- Article 31(b) of the 1975 Community Patent Convention (CPC) proposal:
"The rights conferred by the Community patent shall not extend to [...] acts done for experimental purposes relating to the subject-matter of the patented invention"
- National provisions.
- Different interpretations in Europe?

Selected Case Law

- Monsanto v Stauffer (English Court of Appeal 1985)
- SKF v Evans (English Court of Appeal 1985)
- Clinical Trials I (German Federal Court of Justice 1995)
- Clinical Trials II (German Federal Constitutional Court 1997)
- Auchinloss v Agricultural & Veterinary Supplies
(English Court of Appeal 1998)
- CoreValve v Edwards Lifesciences (English High Court
2009)

Scope of the exemption

- 1) “acts done for experimental purposes”
 - Commercial purposes?
 - 2) “relating to the subject matter of the invention”
 - “On”, not “with” a patented invention.
- The regulatory review exemption.
 - Research tools?

Use of patented inventions in research - problems

1) Application of the experimental use exemption.

Yes: True experimentation on the invention as such.

No: Use of the invention to conduct experiments.

- Need for an extended exemption?

Use of patented inventions in research - problems

2) Access to material.

- Depending on the nature of the invention.
- Physical property controlled by others?
- Commonly available and created easily?

Use of patented inventions in research

- Policy discussions: impediment of research and progress of technology vis-à-vis importance of patents for technical development.
- Extended statutory exemption for research (Belgium, Switzerland).