

**Biotechnology:  
The key provisions of the EPC 2000  
governing what can and can't be  
patented in Europe**

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# EXCLUSIONS - Art 53 EPC 2000

- 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 contrary merely because it is prohibited by law or regulation in some or all of the Contracting States;
  - b) plant or animal varieties or essentially biological processes for the production of plants or animals; this provision shall not apply to microbiological processes or the products thereof;
  - c) methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practiced on the human or animal body; this provision shall not apply to products, in particular substances or compositions for use in any of these methods



# Rule 27

- **Biotechnological inventions shall also be patentable if they concern:**
  - a) biological material which is isolated from its natural environment or produced by means of a technical process even if it previously occurred in nature;**
  - b) plants or animals if the technical feasibility of the invention is not confined to a particular plant or animal variety;**
  - c) a microbiological or other technical process other than a plant or animal variety**



# NOVELTY - Art 54(4) and (5) EPC 2000

- (4) Paragraphs 2 and 3 shall **not** exclude the patentability of any substance or composition comprised in the state of the art, for use in a method referred to in Art 53 (c) [*methods for treatment of the human or animal body ... and diagnostic methods*], provided that its use for any such method is not comprised in the state of the art

= **FIRST MEDICAL USE**

- (5) Paragraphs 2 and 3 shall not exclude the patentability of any substance or composition referred to in paragraph (4) for any **specific** use in a method referred to in Article 53(c) [*methods for treatment of the human or animal body... and diagnostic methods*], provided that use is not comprised in the state of the art

= **SECOND MEDICAL USE**



# Rule 27 EPC 2000

May permit the patenting of:

- Biological material
- Plants and animals
- Microbiological processes



# Rule 28 EPC prohibits on moral grounds

The patenting of:

- Cloning human beings
- Modifying the germ line of human beings
- Use of human embryos for industrial or commercial purposes
- Processes for modifying animals which may cause suffering without any substantial benefit



# Rule 29 EPC

- (1) The human body or the discovery of one of its elements including the sequence or partial sequence of a gene cannot be patented
- (2) An element *isolated* from the human body including the sequence or partial sequence of a gene may constitute a patentable invention
- (3) The industrial application of a sequence or partial sequence must be disclosed



# Rule 30-33 EPC 2000

- IF YOUR APPLICATION INVOLVES A CULTURE DEPOSIT THIS MUST BE MADE BEFORE/ON THE SAME DAY AS YOU FILE AN APPLICATION
- IF YOUR APPLICATION INVOLVES A SEQUENCE LISTING make sure the CORRECT listing is at least in the description then you will have further opportunities to get it into the prescribed format
- If the sequence is omitted or wrong you will not be able to rectify the situation



# **PATENTABLE** ✓

- **Art 54(4) FIRST MEDICAL USE**
- **Art 54(5) SECOND MEDICAL USE**
- **Rule 27 (a) Biological material**
- **Rule 27 (b) Plants or animals**
- **Rule 27 (c) Microbiological processes**
- **Rule 29 (2) An element isolated from the human body but 29 (3) requires that the industrial application of a sequence must be disclosed**



# NOT PATENTABLE

- Art 53 (a) inventions the commercial exploitation of which would be contrary to “ordre public” or morality;
- Art 53 b) plant or animal varieties;
- Art 53 c) methods for treatment of the human or animal body and diagnostic methods practiced on the human or animal body;
- Rule 28 (a) Cloning human beings
- Rule 28 (b) Modifying the germ line of human beings
- Rule 28 (c) Use of embryos for commercial purposes
- Rule 29(d) Processes for modifying animals which may cause suffering without substantial benefit
- Rule 29 (1) The human body or the discovery of one of its elements



# Supplementary protection certificates SPC

- What are they
- What are they for
- What do they do
- When can you get one
- How long does it last



# Thank you for your attention

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