



## What can you patent in biotechnology? – *Video Transcript*

### Exceptions to patentability

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*Welcome to part 2. In the first video, Victoria explained some of the key inclusions when patenting in biotech. So, this video, we'll start to explore what you can't patent.*

*Victoria: Now for the bad news if you're a patent applicant. European patents shall not be granted in respect of:*

- 1. Inventions the commercial exploitation of which would be contrary to "ordre public" or morality*
- 2. Plant or animal varieties or essentially biological processes for the production of plants or animals*
- 3. Methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body*

*Rule 28 EPC provides an illustrative and non-exhaustive list of exceptions to patentability and is to be seen as giving concrete form to the concept of "ordre public" and "morality" in this technical field, i.e. a list of things it would be immoral to patent.*

*Patents shall not be granted for:*

- 1. Processes for cloning human beings*
- 2. Processes for modifying the germ line genetic identity of human beings*

3. *Uses of human embryos for industrial or commercial purposes*
4. *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*

*Number 1 on the list: processes for cloning human beings. This includes processes of embryo splitting, and the creation of another human being with the same genetic information.*

*Processes for modifying the germ line genetic identity of human beings: Any process which modifies the germ line genetically is excluded. Also excluded are processes to produce chimeras from germ cells or totipotent cells of humans and animals.*

*Uses of human embryos for industrial or commercial purposes. A claim directed to a product which, at the filing date of the application, could be exclusively obtained by a method which necessarily involved the destruction of human embryos is excluded from patentability even if the method is not part of the claim. If the invention relies on the destruction of human embryos, at any point in time, it is not patentable. This includes inventions which utilise cell lines derived from methods requiring the destruction of human embryos.*

*I have used the term essentially biological processes frequently and this is because it appears in the EPC and related provisions repeatedly, but what does it mean? This term is used to exclude from patentability plants and animals exclusively obtained by means of an essentially biological process where no direct technical intervention in the genome of the plants or animals takes place an essentially biological process is where the relevant parental plants or animals are merely crossed and the desired offspring selected for, i.e. crossing and selecting during natural breeding methods.*

*The exclusion applies even if technical means are provided serving to enable or assist the performance of the essentially biological steps, i.e. technically assisted crossing and selecting does not render the resulting plants or animals patentable. In contrast, plants or animals produced by a technical process which modifies their genetic characteristics are patentable. Thus, transgenic plants and technically induced mutants are patentable, while the products of conventional breeding are not. Plant varieties are not patentable and so if the claimed subject-matter is directed to a specific plant variety or varieties it is excluded from patentability.*

*The method for the plant's production, be it by recombinant gene technology or by a classical plant breeding process, is irrelevant. For example, plant varieties containing genes introduced into an ancestral plant by recombinant gene technology are excluded from patentability. However, if the plants or animals are not exclusively obtained by means of an essentially biological process, and if the technical feasibility of the invention is not confined to a specific plant or animal variety, the invention is patentable.*

*To summarise: genetically modified plants are patentable in principle if the modification and resulting technical advantage can be applied to more than one plant variety. There are provisions, separate to patent rights, which are available to protect plant varieties.*

*Thanks for watching. In part 3, we'll have explore the key considerations when looking at patents relating to surgery, therapy and diagnosis.*