



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

Therapy, surgery and diagnosis: avoiding patent pitfalls

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Welcome to part 3. There are a lot of innovators searching for new ways to fight diseases and save lives. But patenting in this area requires some key ethical and moral considerations around the human body. So, let's go to Victoria as she breaks down looking at patent relating to surgery, therapy and diagnosis.

Victoria: The EPO's approach to patentability in the field of medicine is based on the underlying principle that medical and veterinary practitioners should be free to use their skills and their knowledge of the best available treatments to achieve the utmost benefit for their patients, uninhibited by any worry that some treatment might be covered by a patent let the doctors do what they got to do.

The EPC therefore includes a general exclusion for medical methods carried out on the body: "European patents shall not be granted in respect of ... methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body".

The exclusion does not apply to products, in particular substances or compositions, for use in such methods. So, although a "method of treatment" is not patentable in Europe, a substance or composition may be patented for a specific use in a method of surgery, therapy or diagnosis. This leads to the "purpose-limited product" claim, a medical use claim.

In summary, methods of treatment are not patentable, but products used in such methods can be protected using medical use claims. Medical use claims are discussed in more detail as a separate topic.

A diagnostic method is excluded from patentability if it is carried out on the human or animal body

A diagnostic method includes the following steps:

- 1. Examination phase (e.g., collecting data)*
- 2. Comparison of the data to standard values*
- 3. Finding of significant deviation (e.g., a symptom)*
- 4. Attribution of the deviation to a particular clinical picture (e.g., making a diagnosis)*

A claim to a diagnostic method is patentable if it does not include any one of these steps, But omitted steps must not be essential to achieving the technical effect of the invention. A diagnostic method carried out separate from the body may be patentable. A diagnostic method carried out on an in vitro tissue sample is not carried out on the human or animal body and is considered patentable.

Examples of the types of methods that are patent-eligible include performing a diagnostic test on a blood sample or a treatment on an organ tissue before transplantation. However, treatment of blood by dialysis where the blood is returned to the patient would be excluded from patentability, as the patient would have to be present during the treatment.

In practice, it is recommended to include at least one technical in vitro step and omit any non-essential steps that are practised on the human body. For example, in a method that comprises a method of diagnosis based on identifying a particular biomarker in a blood sample, the step of actually obtaining the sample from a patient should be omitted from the claimed method, and the method may instead recite performing the method "on a sample obtained from a subject".

In summary - ensure your claim does not include all four of the steps and do not include steps that are carried out on the human body.

Thank you for watching. Join us in the final part of this course, when we look at medical use claims.