



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

Patent eligible subject matter

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Video 1: Patent eligible subject matter

Welcome back to Academy by PatSnap, and this course: “What can you patent in biotechnology?”. Biotech is one of the most active industries for patents. But issues around morality make it also one of the most complicated. So, in this course, we will take a look at what may be eligible for patenting and what may be excluded.

To guide us through this topic, we’ve enlisted the help of an expert from one of the world’s leading intellectual property firms.

Victoria: My name is Victoria Randall, I’m a senior patent attorney at Finnegan Europe LLP. We are the European branch of a large US firm specialising in intellectual property. I work in the field of biotech and I handle a wide range of subject matter, with a focus on antibodies, vaccines and all areas of genetic modification and manipulation.

In this course we are going to cover the biotech exclusions and exemptions and medical use claims.

Many of examples in this course are given from a European patent perspective. For additional information on patenting in biotech in the US and other jurisdictions, check the additional resources below.

Patenting in the Biotech field can be fraught with ethical and moral considerations but in principle, biotech inventions are patentable under the EPC. What is deemed patentable is governed by the provisions within the EPC. The European Biotech directive is used as a supplementary means of interpretation.

So . . . let's start with the good news for patent applicants. Together these provisions provide a non-exhaustive list of biotech inventions that are considered patentable in principle. The three listed categories are:

Biological material which is isolated from its natural environment or produced by means of a technical process even if it previously occurred in nature

Plants or animals if the technical feasibility of the invention is not confined to a particular plant or animal variety, and if said plants or animals are not exclusively obtained by means of an essentially biological process

A microbiological or other technical process, or a product obtained by means of such a process, other than a plant or animal variety

First on the list . . . Biological material which is isolated or produced by a technical process.

Biological material may be considered patentable even if it already occurs in nature. Although the human body, at the various stages of its formation and development, and the simple discovery of one of its elements, are not patentable, an element isolated from the human body or produced by means of a technical process, which has an industrial application may be patentable, even if it is identical to that found in nature.

For example, a gene sequence with an industrial application may be patentable.

Second on the list . . . Plants or animals if the technical feasibility of the invention is not confined to a particular plant or animal variety, and if said plants or animals are not exclusively obtained by means of an essentially biological process.

I will come back to what is meant by plant or animal varieties and EBP later, but put simply EBPs are natural breeding methods involving crossing and selecting and a variety is a single taxon in the lowest known rank – crystal clear if you are a plant or animal breeder. plants or animals are patentable provided that the application of the invention is not technically confined to a single plant or animal variety. The plants or animals must not be exclusively obtained by means of an essentially biological process.

If a technical feature of a claimed plant or animal, for example a single nucleotide change, might be the result of either a technical intervention, for example directed mutagenesis, or an essentially biological process, for example a natural allele, a disclaimer is necessary to delimit the claimed subject-matter to the technically produced product, thus excluding the natural allele. The subject-matter of a claim covering but not identifying plant varieties is not a claim to a variety, and therefore is not excluded from patentability.

Third on the list . . . A microbiological or other technical process, or a product obtained by means of such a process other than a plant or animal variety.

"Microbiological process" means any process involving or performed upon or resulting in microbiological material. This provision is rather vague and can be thought of as the miscellaneous category of patentable biotech inventions. A patentable biotech invention will probably be categorised here if it does not fall within one of the other exclusions or exemptions.

Thank you for watching. In part 2, we will cover exceptions to patentability. Don't forget to check the additional resources below.