



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

Medical use claims

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Welcome to part 4. So far, we have learned about inclusion, exceptions and some key considerations when looking at patents relating to surgery, therapy and diagnosis. For the final part, we'll take a look at medical use claims.

Medical use claims are a special type of purpose-limited product claim. Medical use claims are an exception to the normal rules of novelty – i.e. medical use claims can be directed to known substances. Although claims to methods of treatment are not patentable, medical use claims directed to a composition for use in a method of treatment may be patent eligible.

Where a substance or composition is already known, it may still be patentable if the known substance or composition was not previously disclosed for use in a method of surgery, therapy or diagnosis. This is known as a first medical use claim and follows the formal "Product X for use as a medicament".

Where a substance or composition is known for a first medical use, it may still be patentable for any second or further use. This is known as a second medical use claim and takes the format: "Product X for the treatment of disease Y" or "Product X for use in a method of treating disease Y". The claim must indicate a real disease to be treated, it must relate to defined and real treatment of a pathological condition.

Medical use claims allow for an exception from the general principle that product claims can only be obtained for novel products. Even though this affords a special case for novelty, medical use claims must still fulfil the other requirements of patentability, in particular inventive step.

A claim directed to the further therapeutic use of a substance/composition must indicate the illness or disease to be treated, the nature of the therapeutic compound used for that purpose and, if relevant for establishing novelty and inventive step, the subject to be treated. If the further therapeutic use relates to a different therapy of the same disease using the same substance or composition, the claim must also define all technical features of the therapy giving rise to the desired technical effect.

The treatment of a disease with a substance or composition which is already known to be used for treating the disease, where the only difference from the known treatment is in the dosage regime, is a specific further medical use that can be claimed and is patent eligible.

Thus, therapeutic uses of a substance or composition may be based not only on the treatment of a different disease but also on the treatment of the same disease by a different therapeutic method differing for example in the dosage, administration regime, group of subjects or route of administration.

Medical use claims must be structured according to a specific format.

- *First medical use would take the format “Product X for use as a medicament”*
- *Second medical use would be “Product X for the treatment of disease Y; or Product X for use in a method of treating disease Y”*
- *Where the novel and inventive feature is the dosage, it would be “Product X for use in a method of treating disease Y, characterized in that product X is administered at a dose of 3mg/kg*
- *Where the novel and inventive feature lies in the administration regime, the claim would take the format “composition comprising X for use in treating disease Y wherein the composition is administered 3 times daily”*
- *If it's the group of subjects that renders the claim novel or inventive, the claim format would be “substance X for use in a method of treating a subject with disease Y, wherein the subject is refractory to chemotherapy” for example.*
- *Where the novel or inventive feature is the route of administration, it would be “a composition comprising X for treatment of disease Y, wherein the composition is administered topically”*
- *Such claims must still satisfy the requirements of inventive step and claim features must provide a non-obvious technical contribution.*

Swiss type claims are no longer allowed if the application has a filing or earliest priority date of 29 January 2011 or later. They took the format “Use of a substance X for the manufacture of a medicament for therapeutic application Y”.

The principles of medical use claims apply only to substances and compositions

A claim directed to a device for an intended medical use (e.g. pacemaker or implantable chemical sensor) must be construed as claiming a device which is suitable for that medical use, i.e. the claim is not rendered novel by reciting a new medical use for the device, the device itself must be novel and inventive. Medical use claims and the associated exceptions do not extend to medical devices.

That concludes this course on biotech inclusions and exemptions. If you have any questions, feel free to contact me, Victoria Randall at Finnegan Europe LLP. Thanks for watching.

Well done for completing this course. Thanks to Victoria for providing us with her insight, don't forget to check the links below for additional information, materials and resources. Now that you know what can and can't be patented, how might you go about commercialising your biotech innovations? Well we've got you covered, and would recommend our course, made in collaboration with Pete Hotten of the Royal Society, “Commercialising ideas in life sciences”. Otherwise, see you next time on Academy.