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Medical Inventions in Europe

Methods of treatment of the human or animal body by surgery or therapy and diagnostic methods practiced on the human or body are excluded from patentability in Europe (see Art. 53 EPC).

However, such methods of treatment can still be protected in the form of a first medical use claim or a second medical use claim. Medical use encompasses use in therapy, use in in vivo diagnostics or use in surgery. These provisions are set out in Art. 54(4) and Art. 54(5) EPC.

First Medical Use

A first medical use claim can be obtained for a substance or composition that was already known, but was not previously used in therapy, surgery, or in vivo diagnostics.

For example, consider that Substance X is known, but was previously not used in medicine. The following claims would be allowable, provided the invention also involves an inventive step.

Substance X for use in medicine

Substance X for use in therapy

Substance X for use as a medicament

Substance X for use in in vivo diagnostics

Substance X for use in surgery

A first medical use claim protects that substance for use in treatment or diagnosis in medicine generally, and therefore provides protection for use of that substance against all diseases or for all use in surgery and in vivo diagnostics, depending on how the claim is formulated.

Second Medical Use

A second medical use claim can be used to obtain patent protection for an invention involving a substance or composition that is already used in medicine, but is now claimed for a different medical use.

Different disease

One type of second medical use claim is a claim to a substance or composition for use in the treatment of a different disease.

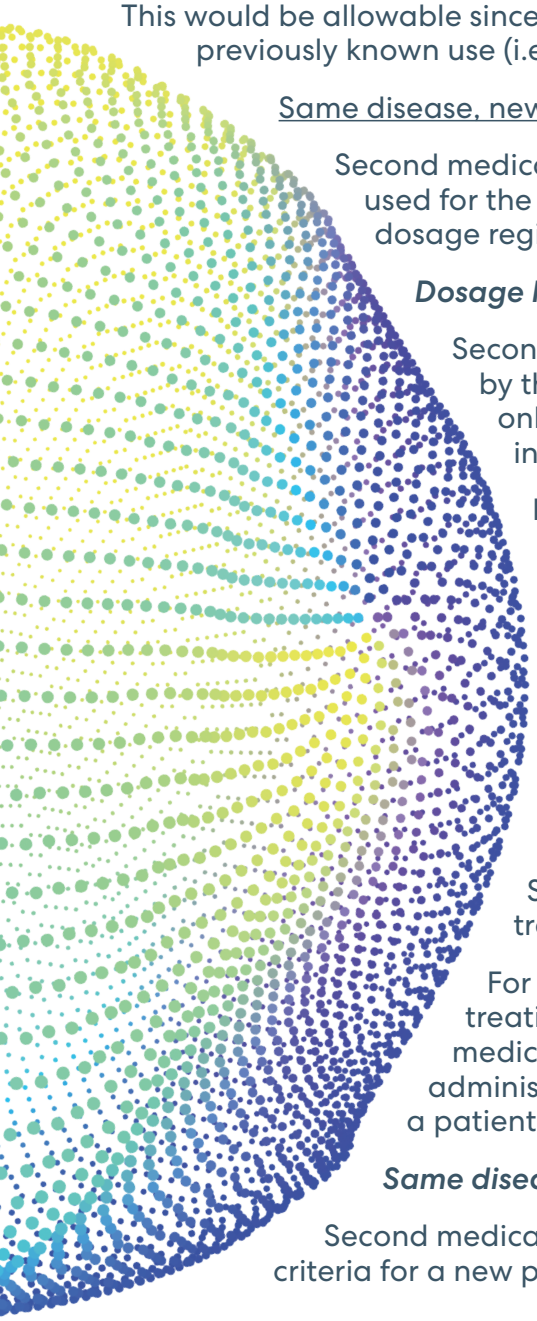
For example, if Substance X had previously been described for use in cancer, and more specifically brain cancer, the following claims would be allowable provided the invention also involves an inventive step.

Substance X for use in [a method of] treating or preventing cardiovascular disease.

This would be allowable since cardiovascular disease is a different disease to the previously known use (i.e., cancer).

Substance X for use in [a method of] treating or preventing leukemia.

This would be allowable since leukemia is a specific type of cancer which is different to the previously known use (i.e., brain cancer).



Same disease, new therapeutic use

Second medical use claims can also be obtained for substances and compositions used for the same disease, but for a new specific use. This may be a different dosage regime, different mode of administration, or a new patient group.

Dosage Regime

Second medical use claims can be obtained for a different treatment by therapy of the same disease, even where a dosage regime is the only different or distinguishing feature (see G2/08). A dosage regime includes both the amount and timing of administration.

For example, where a Substance X had previously been described for use in the treatment or prevention of disease Y, using a dosage of at least 5 mg every day, the following claim would be acceptable provided the dosage regime is new and involves an inventive step:

Substance X for use in the treatment or prevention of disease Y, wherein substance X is administered at a dosage of 0.1-1mg every 2 hours.

Same disease, new mode of administration

Second medical use claims can be obtained for a different treatment of the same disease, with a new mode of administration.

For example, where substance X had previously described for use in treating or preventing disease Y by intravenous administration, a second medical use claim could be obtained for use in disease Y by intramuscular administration, provided the new administration is non-obvious and offers a patient benefit.

Same disease, new patient group

Second medical use claims can also be obtained for a new patient group. The criteria for a new patient group is set out in T 1491/14 as:

- The patient group was not previously disclosed in the relevant prior art
- The patient group is distinguished from those in the prior art by their physiological or pathological status
- There is a functional relationship between the physiological and pathological status and the therapeutic treatment and thus the selection of the patients it not arbitrary

An example situation is where the use of a drug for a particular disease is known, but it is found that a sub-group of patients with a particular biomarker respond particularly well to treatment with this drug for this disease. Another example case is provided in T 734/12; here, the second medical use of the antibody rituximab in the treatment of rheumatoid arthritis in a patient group that "experiences an inadequate response to a TNF alpha-inhibitor" was considered sufficiently distinguishable from the patient group known in the prior art.

FAQs

Can the disease be functionally defined?

Yes, it is possible to define the disease for a second medical use claim in functional terms (rather than claiming a specific disease), but only if it is common general knowledge which diseases fall within that functional definition, or if the patent itself provides testable criteria for the skilled person to determine which diseases fall within that definition (see T241/95). When drafting second medical use claims functionally, it is therefore advisable to define some examples of such conditions in the specification.

Am I allowed more than one medical use claim in the same application?

Yes. If you discover that Substance X can be used to treat a specific disease, but Substance X has not been used in any therapy before, you can obtain both first and second medical use claims in the same patent.

Different second medical use claims can also be obtained (i.e., for different diseases, or for the same disease but a different therapeutic use), provided the claims are unified and share the same overall inventive concept.

My claim was drafted in the US as a method of treatment claim. Can I still protect this in Europe?

Yes. It is permissible to convert a Method of Treatment claim or a Swiss-style claim (i.e. Use of Substance X for the manufacture of a medicament for therapeutic application Y) into a medical use format that is acceptable in Europe. The claim can be converted into a suitable format upon filing the European application, or during prosecution.

For example, a US-drafted application including the claim:

> "A method of treating disease Y, the method comprising administering Substance X to a subject"

can be readily converted into the claim:

> *"Substance X for use in a method of treatment of disease Y, the method comprising administering to the subject Substance X"*

for prosecution in Europe.

Can I obtain a first or second medical use claim for in vitro diagnostic use?

No. First and second medical use claims can only be obtained for diagnostic methods that take place *in vivo*, i.e., practiced on the human or animal body. If the diagnostic method occurs outside the human or animal body (i.e. *in vitro* or *ex vivo*), the method of diagnosis is no longer excluded from patentability in Europe and first and second medical use claims cannot be used. *In vitro* diagnostic claims can instead be formulated as:

> *Use of substance X in a method of diagnosis in vitro of disease Y, the method comprising...* or

Method of diagnosing disease Y in vitro, the method comprising use of substance X...

What supporting information or evidence do I need in the patent in support of a medical use claim?

It is established case law that in order to meet the requirements of sufficiency, the patent has to plausibly show that the substance or composition can be used for that therapeutic use. The application must therefore provide suitable evidence for the claimed therapeutic effect, or it must be derivable from the prior art or from common general knowledge (see T 1437/07).

It is therefore advisable to provide as much data as possible in the application as filed in support of this therapeutic effect. This may be any type of experimental data and does not need to be the result of a clinical trial. While post-published evidence may also be taken into account, this is only to the extent that it backs up the findings already made *plausible* in the application as filed.

If there is no data in the application as filed, you will have to rely on prior art or common general knowledge to meet the threshold of plausibility. However, relying so heavily on the prior art or common general knowledge may undermine the arguments for inventive step.

Can I obtain a first or second medical use claim for a device?

No. Medical use claims cannot be obtained for a known device used in a new therapeutic use. This is because first and second medical use claims are limited to substances or compositions.

T1758/15 defines a substance or composition as a product that achieves a direct therapeutic effect by a chemical, as opposed to a physical, interaction with the body. In this particular case, a filler material that protected sensitive tissue from radiation, by mechanical displacement of the sensitive tissue, was considered to behave as a device. As a result, medical use claims weren't allowable.