



Medical use claims

Anne Schouboe, Plougmann & Vingtoft a/s

Outline of presentation

Which inventions related to a new use of a compound can be patented?

Which of these patents can be enforced in Europe?

Which inventions related to a diagnostic method can be patented in Europe?

Art. 52(4) and Art. 54(5) EPC

Art. 52(4) EPC

“Methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body shall not be regarded as inventions which are susceptible of industrial application This provision shall not apply to products, in particular substances or compositions, for use in any of these methods.”

Art. 54(5) EPC

“The provisions of paragraphs 1 to 4 shall not exclude the patentability of any substance or composition, comprised in the state of the art, for use in a method referred to in Art. 52, paragraph 4, provided that its use for any method referred to in that paragraph is not comprised in the state of the art.”

1st medical use

Example of how to claim a 1st medical use:

Gotchalism toxin for use as a medicament

Gotchalism toxin for use in the treatment of migraine headaches



2nd medical use

Use of a known medicament for a new and inventive purpose (Swiss format):

Use of *Gotchalism* toxin type A for the preparation of a composition for the treatment of muscle spasms



Enforcement of medical use patents in Europe

Taxol case (Bristol-Myers Squibbb v Baker Norton Pharmaceuticals)

Use of taxol and sufficient medications to prevent severe anaphylactic reactions, for manufacturing a medicamentation for simultaneous, separate, or sequential application for the administration of from 135mg/m² up to 175 mg/m² taxol over a period of about 3 hours or less as a means for treating cancer and simultaneously reducing neutropenia

Court of Appeal held that this claim defined an improvement in the method of administering an existing treatment.

Japan

The first and second medical use claim formats are widely accepted, but the recommended claim format varies from country to country.

As an example, the recommendation with regard to Japan regarding 2nd medical use is pharmaceutical composition format limited by the second use, i.e.

Pharmaceutical composition comprising *Gotchalism* toxin Type A for treatment of muscle spasms

Diagnostic methods

T385/86 (Bruker)

A method to obtain information (data) from a live human or animal body is not excluded from patenting by Art. 52(4) EPC, if the obtained information only provides interim results, which not in themselves make it possible to take a decision concerning treatment.

T964/99 (Cygnus)

A step of iontophoretically sampling a substance from the living human or animal body for diagnostic purposes has to be considered a diagnostic method within the meaning of Art. 52(4) EPC.

Diagnostic methods - example

A method of determining if a patient can be treated successfully with

Gotchalism toxin, the method comprising the following steps:

- (a) obtaining a blood sample from a patient;
- (b) contacting said blood sample with ...
- (c) ...

Steps (a) and (b) of this claim should be revised e.g. to read

(a) contacting a blood sample obtained from a patient with ...

Conclusion with regard to medical use claims

A method of treatment concept can often be written as a 1st medical use or, more commonly, a 2nd medical use claim

but

in order for the invention to be patentable and the claim to be enforceable the invention has to be novel, inventive, credible and not excluded from patenting.

Conclusion with regard to methods of diagnosis

A method of diagnosis that is not practised on a human or animal body is allowable.

The important issue is to formulate the inventive concept so that the claim does not have a single impermissible treatment step performed on a human or animal body.

Conclusion: Don't touch!

