Patentability of inventions in the pharmaceutical field
EPO Boards of Appeal Case Law

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Overview

EPC provisions on:

• First medical use

• Further medical use
  - allowable and non-allowable claim formats
  - the therapeutic indications
  - G2/08

Conclusions on medical use
EPC 2000 provisions for first and further medical use

Art. 53(c) EPC

• European patents shall not be granted in respect of methods for the treatment of the human or animal body by surgery, therapy and diagnostic methods practised on the human or animal body; this provision shall not apply to products, in particular substances or compositions, for use in any of these methods.

Exception regime

Art. 54(4) EPC: substances or compositions already known per se can be patented for use in one of the above mentioned methods. (1st medical use)

Art. 54(5) EPC: if they were already known as medicines they are also patentable for a specific use not comprised in the state of the art. (further medical use)
First medical use

1st medical use claim:

**Compound X for use as a medicament.**

In non-medical fields "for" defines suitability and is not limiting
cup for drinking coffee = cup for drinking tea (any cup)

In medical use claims "for use" is limiting according to Art. 54(4) EPC

**Medical use renders claim novel if no previous generic or specific medical use disclosed.**

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Second medical use claims

2nd medical use claim:

**Compound X/ composition comprising X for use in a method for the treatment of disease Y.**

Other allowable claim formats:
Compound X/ composition comprising X for use in a method of treating inflammation.
Compound X/ composition comprising X for use in the treatment of inflammation.

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In pending applications (filed before 29.01.11) also the Swiss-type format:
Use of compound X for the manufacture of a medicament for the treatment of disease Y.
Second medical use claims

Non allowable formats

Compound X for treating disease Y
Compound X for a method of treating Y
Compound X in a method of treating Y
Anti-inflammatory composition comprising Compound X.

Real nature of the use is not clearly defined in the sense of Art. 84 EPC. The specific use is therefore not establishing novelty.

Second medical use

• The exception of Art. 54(5) EPC is also applicable to compounds/compositions for use in an in vivo diagnostic method or a surgical method

• but not applicable to devices for use in a surgical method

• Purpose-limited product claims are only allowable for uses covered by Art. 53(c) EPC. If a claim encompasses a use for a method NOT excluded by Art. 53(c) EPC the purpose (“for use”) loses its limiting value.

• Examples:
• Composition X for use as an antifungal.
• Composition X for use as a contrast agent for imaging tumoral cells.
Second medical use: the indication

- Therapy encompasses:
- Healing or basic curing
- Symptomatic treatment
- Alleviating pain in case of ordinary natural situations like dysmenorrhea, cancer
- Prophylaxis

- If a use is not therapeutic a claim format according to Art. 54(5) EPC is not acceptable; a non-medical use claim is possible.

Example:
Composition A for use in improving skin elasticity.
As the use is cosmetic and not therapeutic the use is not limiting. Claim lacks novelty over any disclosure of compound A suitable for skin elasticity improvement.

Second medical use: distinguishing features

Art. 54(5) EPC explicitly allows further patent protection of substances or compositions already known as medicines provided their use in a method under Art. 53(c) EPC be specific and not comprised in the state of the art.

A specific new use may be the treatment of
- a different disease
- a new group of patients (T19/86; T233/96)
- a new mode of administration(T51/93)

- G2/08 answers the question if a new dosage regimen for the treatment of the same illness can establish novelty in a medical use claim.
The Board of Appeal had to decide on the patentability of a claim directed to:

"The use of nicotinic acid ... for the manufacture of a sustained release medicament for use in a treatment by oral administration once per day prior to sleep, of hyperlipidaemia characterized in that ...", where the only feature which was not known from the prior art was the dosage regime.

Decision of the Examining Division

- The claim is in the "Swiss-type format" as allowed in the decision of the Enlarged Board of Appeal G5/83. The only distinguishing feature in the claim which was not yet disclosed in the prior art was the feature relating to a specific drug regimen.

- The Examining Division concluded that the specific drug regime i.e. once per day prior to sleep, reflected a medical activity excluded from patentability under Art. 52 (4) EPC 1973, which could not therefore establish novelty. The Examining Division thus was of the opinion that this claim was anticipated by the prior art.
Reasons for the referral of decision T1319/04 to the Enlarged Board of Appeal

It was not clear, whether the only distinguishing feature by oral administration once per day prior to sleep could establish novelty, because in previous decisions (T317/95, T 56/97, T584/97) the Boards of Appeal had taken different views on the issue of whether the prescribing and modification of a drug regimen for known medical treatments represents a further medical indication from which novelty could be derived.

Questions referred to the Enlarged Board of Appeal

(1) Where it is already known to use a particular medicament to treat a particular illness, can this known medicament be patented under the provisions of Art. 53(c) and 54(5) EPC 2000 for the use in a different, new and inventive treatment by therapy of the same illness?

(2) If the answer to question 1 is yes, is such patenting also possible where the only novel feature of the treatment is a new and inventive dosage regime?

(3) Are any specific considerations applicable when interpreting and applying Articles 53(c) and 54(5) EPC 2000?
Applicable law

The patent application was filed in 1994 and was still pending on 13 December 2007, when the EPC 2000 entered into force. Therefore according to the transitional provisions the revised Articles 53(c) and 54(5) EPC 2000 apply.

EPC 2000 provisions for first and further medical use

Art. 53(c) EPC
• European patents shall not be granted in respect of methods for the treatment of the human or animal body by surgery, therapy and diagnostic methods practised on the human or animal body; this provision shall not apply to products, in particular substances or compositions, for use in any of these methods.

Art. 54(5) EPC
• This Article explicitly allows further patent protection of substances or compositions already known as medicines provided their use in a method under Art. 53(c) EPC be specific and not comprised in the state of the art.
Article 54(5) EPC does not define the nature of the specific (further therapeutic) use of a substance or composition. There appear two ways of construing the requirement:

- the further claimed use need not necessarily consist in a different disease
- only a new disease not yet treated by the known substance or composition can constitute a specific use within Art. 54(5) EPC

"Any specific use"

The Enlarged Board of Appeal came to the conclusion that "any specific new use" within the meaning of Art. 54 (5) EPC cannot be ex officio limited to a new indication; it can be either another disease or one or more steps pertaining by nature to a therapeutic method which may not be claimed as such.
Answer to the referred questions:

(1) Where it is already known to use a medicament to treat an illness, Art. 54(5) EPC does not exclude that this medicament be patented for use in a different treatment by therapy of the same illness.

(2) Such patenting is also not excluded where a dosage regimen is the only novel feature claimed which is not comprised in the state of the art.

(3) Where the subject matter of a claim is rendered novel only by a new therapeutic use of a medicament, such claims may no longer have the format of a so called Swiss-type claim as instituted by decision G5/83.

Novelty and non-obviousness of a dosage regime

- The dosage regime must not only be verbally different from what is described in the state of the art but must also reflect a different technical teaching.
- Novelty and inventive step of the claimed subject-matter must be determined according to established case law.
- If the claimed modalities of a dosage regimen consist in a selection within the teaching of a broader prior art, the criteria developed in the case law for the novelty of selection inventions must be fulfilled.
- A new technical effect caused by said dosage regimen shall be considered when examining inventive step under Art. 56 EPC.
No Swiss-type format in future patent applications

In decision G2/08 the Enlarged Board of Appeal held, that, where the subject matter of a claim is rendered novel only by a new therapeutic use of a medicament, such claim may no longer have the format of a Swiss-type claim as instituted by decision G5/83 as Art. 54(5) EPC 2000 now permits purpose-related product protection.

The prohibition on Swiss type claim only applies to applications having a filing date or, if priority has been claimed, earliest priority date of 29.01.2011 or later. The relevant date for a divisional application is the filing or priority date of the parent application.

G2/08 enters into force without retroactive effect; thus patent applications which are still pending on 29.01.2011 shall be treated under the legal frame work established by G5/83.

Issues in opposition and litigation

- Is the prescription of doctors or recommendation of pharmacies on how to apply a known medicament, which describe the dosage regimen feature in a claim, novelty destroying?
- What will constitute a prior use?
- Who can be an infringer of a claim for a dosage regimen? The pharmacies when specifying the modality of the use of a known medicament as claimed?
Thank you for your attention