

First and second medical uses under the European Patent Convention

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Overview

- General provisions
- First medical use
- Second and further medical uses
 - Under EPC 1973
G1/83, G5/83 and G6/83 (1984)
 - Under EPC 2000 (in force as of 13.12.2007)
G 2/08 (2010)

General provisions



Patentable inventions: Article 52 EPC

(1) European patents shall be granted for any **inventions**, in **all fields of technology**, provided that they are **new**, involve an **inventive step** and are susceptible of **industrial application**.

Categories

- Product
- Process
- Apparatus
- Use

General provisions



Exceptions to patentability: Article 53 EPC

European patents shall not be granted in respect of:

...

- (c) **methods for treatment** of the human or animal body by **surgery** or **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.

→ **Patent protection** available for **substances (product)** or for their **manufacture (process)** in accordance with **Article 52 EPC**

→ **No patent protection** for **medical methods** because of **Article 53(c) EPC**

excluded: e.g.

“method of treatment of disease Y with the substance X”

“use of substance X for the treatment of disease Y”

First medical use



Article 54(4) EPC

“Paragraphs 2 and 3 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 Article 53(c),** provided that **its use for any such method** is not comprised in the state of the art.“

First medical use

Article 54(4) EPC

Purpose-related product protection in the medical field

Claim format:

e.g.

- *"Compound X for use as a medicament"*
- *"Compound X for use in a method for the treatment of disease Y"*

Second and further medical uses

EPC1973

- No provision/mentioning of second or further medical uses in EPC 1973

- Enlarged Board of Appeal Decisions
G 1/83 (German), **G 5/83** (English) and **G 6/83** (French) of 05.12.1984, OJ EPO 1985, 60, 64, 67



A European patent may be granted with claims directed to the **use** of a substance or composition **for the manufacture of a medicament** for a **specified new and inventive therapeutic application**.

→ “Swiss-type” claim

Second and further medical uses

EPC1973

- "Swiss-type" claim = use-claim:

"use of compound X for the manufacture of a medicament for the treatment of disease y"

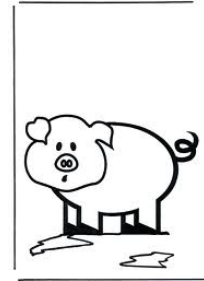
- novelty derived from the new therapeutic use of the medicament → **"special approach to the derivation of novelty"**
- No definition of "specified new and inventive application"
 - Treatment of a **different disease**? → yes
 - Treatment of the **same disease**? → subsequent case law of the Boards of Appeal
Different patient group, different mode of administration, different technical effect in the body

Second and further medical uses

EPC1973

Different group of subjects treated

T19/86 (1987) – Pigs II



- Second medical use with same compound for **same illness** but different group of patients? → yes
- Concept confirmed in several decisions
(T893/90, T885/91, T233/96, T584/97, T1031/00, T486/01, T836/01, T485/99, T708/02 and T1399/04)

Second and further medical uses

EPC1973

Different group of subjects treated

Specific conditions developed in **T233/96** (2000):

- 1) Group must be distinguishable with respect to physiological or pathological status
- 2) Group must not overlap with previously treated group and
- 3) Group must not be selected arbitrarily – relationship between physiological or pathological status and therapeutic effect must exist

T1399/04: only criterion 1)

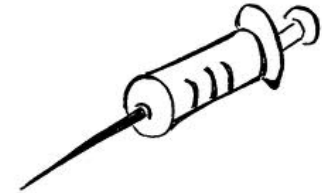
Second and further medical uses

EPC1973

Different route or mode of administration

T51/93 (1994)

- Second medical use with same compound for same illness but different mode of administration? → yes
- Application: **subcutaneous** administration
Known: **intramuscular** administration
- Subsequent decisions **T138/95, T233/96, T584/97**



Second and further medical uses

EPC1973

Different technical effect in the body

T290/86 (1990)

- Second medical use with same compound for same therapeutic purpose but based on different technical effect?
→ yes
- Claimed invention: Lanthanum salts for removal of plaque from human teeth \leftrightarrow Prior art: Lanthanum salts for reducing solubility of tooth enamel in acids
- Approach restricted by later case law: an unsuspected property of a known substance does not necessarily translate into a novel use of that substance → truly new application necessary

Second and further medical uses

EPC1973

Different dosage regimen?

Same compound, same disease but e.g.

- different dosages - different quantity and/or frequency
- different duration
- different schedule of administration
- different chronological order/course of administration
- different timing

Second and further medical uses

EPC1973

Different dosage regimen?

Patent protection available?

- Yes/positive tendency:

T1020/03 (2004), **T 292/04** (2005), **T 1399/04** (2006),
T 380/05 (2006), **T 36/04** (2006), **T 1074/06** (2007)

- No/ question unanswered:

T570/92 (1995), **T317/95** (1999), **T56/97** (2001), **T584/97**
(2001), **T485/99** (2004)

Second and further medical uses



EPC2000 (as of 13.12.2007)

Article 54(5) EPC

Paragraphs 2 and 3 shall also not exclude the patentability of any substance or composition referred to in paragraph 4 for **any specific use** in a method referred to in Article 53(c), provided that **such use** is not comprised in the state of the art.

→ Purpose-related product protection

→ Claim format:

"Compound X for use in a method for the treatment of disease Z"

Second and further medical uses

EPC2000

T1319/04 (2008):

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 Articles 53(c) and 54(5) EPC 2000 for 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 special considerations** applicable when interpreting and applying Articles 53(c) and 54(5) EPC 2000?"

Second and further medical uses

EPC2000

G 2/08

Decision of the Enlarged Board of Appeal
dated 19 February 2010, OJ 2010, 456



Order

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

→ Wording of Art. 54(5): "any specific use"

→ *Travaux préparatoires* to EPC2000

Second and further medical uses

EPC2000

G 2/08

Decision of the Enlarged Board of Appeal
dated 19 February 2010, OJ 2010, 456



Order

- "Question 2: Such patenting is also **not excluded** where a **dosage regime** is the only feature claimed which is not comprised in the state of the art."
 - "...there is no reason to give to a feature consisting in a new dosage regime of a known medicament a different treatment than the one given to any other specific use acknowledged in the case law"
 - Novelty and inventive step!

Second and further medical uses

EPC2000

G 2/08

Decision of the Enlarged Board of Appeal
dated 19 February 2010, OJ 2010, 456



Order

- "Question 3: 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 so-called **Swiss-type claim** as instituted by decision G 5/83.
A time limit of **three months after publication** of the present decision in the Official Journal of the European Patent Office is set in order that future applicants comply with this new situation."
 - Publication date: 28.10.2010 → Non-acceptance of Swiss-type claims in patent applications with a filing/priority date of 29.01.2011 or later

Summary

- Exclusion of medical **methods**: Art. 53(c) EPC
- First medical use: Art. 54(4) EPC
- **Purpose-related product protection**
- Second and further medical uses
 - Under EPC 1973: „**Swiss-type**“ claim
G1/83, G5/83 and G6/83 (1984)
 - Under EPC 2000 (in force as of 13.12.2007):
Art. 54(5) EPC: **Purpose-related product protection**
G 2/08 (2010)
 - "any" specific use not comprised in the state of the art
may be eligible for patent protection

Thank You

