First and Second Medical Use
An Overview of EPO Case Law and Practice

Points for Discussion

- Claim construction
- “Mixed use”: therapeutic vs. non-therapeutic
- Novelty (further features)
- Clarity
- Absence of credible effect: Article 83 EPC vs. Article 56 EPC
- Late-filed evidence
Peculiarity of pharmaceutical inventions - methods

Article 53 EPC - Exceptions to patentability

- "European patents shall not be granted in respect of...
  (a) ...
  (b) ...
  (c) methods for the treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body;
  ...
"

- Reason:
  Ensure that doctors/veterinarians are not inhibited by patents in the practice of medicine (G5/83; T116/85; T82/93)

Peculiarity of pharmaceutical inventions - uses

- In non medical patent language: "for" means "suitable for"
  glass for drinking water ≡ glass for drinking juice

- In medical patent language: "for" is purpose limiting and is expressed as "for use"
Claim construction

Purpose-limited product claim

“Compound X for use in medicine” (Article 54(4) EPC)

⇒ first medical use
⇒ claim limited by medical purpose

“Compound X for use in the treatment of disease Y” (Article 54(5) EPC)

⇒ second and further medical use
⇒ claim limited by therapeutic indication

Claim construction

First medical use

Article 54(4) EPC

“Paragraphs 2 and 3 shall not exclude the patentability
do not comprised in the state of the art,of any substance or composition comprised in the state of the art,for use in a method for use in medicine referred to in Article 53(c), provided thatsuch use is not comprised in the state of the art”

Product: “Substance X”

↑ prima facie not novel over

Non-medical use: “Substance X (suitable) for use in agriculture”

↑ novel over

1st medical use: “Substance X for use in medicine”
Claim construction

Second and further medical use

**Article 54(5) EPC**

>Paragraphs 2 and 3 shall also not exclude the patentability of any **substance or composition** comprised in the state of the art, for any specific **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**

1st medical use:  "**Substance X for use in medicine**"

↑ novel over

2nd medical use:  "**Substance X for use in treating disease Y**"

↑ novel over

**Further medical use:**  "**Substance X for use in treating disease Z**"

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Claim construction

**Purpose-limited product claim according to A54(5) EPC 2000**

"**Compound X for use in the treatment of disease Y**"

➢ only applicable to cases pending on or filed upon entry into force of EPC 2000 (≥13 December 2006)

➢ claims **granted** under EPC 1973 (<13 December 2006) to be construed as claims directed to a first medical use (for use in medicine)
Claim construction

Second and further medical use (according to G5/83)

G5/83
claims to the use of a substance for the manufacture of a medicament
for a specified new and inventive therapeutic application allowable,
even in a case in which the process of manufacture as such
does not differ from known processes

Manufacture: "Use of substance X for the manufacture of a
medicament"

→ novel over

1st medical use: "Substance X for use in medicine"

→ novel over

2nd medical use: "Use of substance X for the manufacture of a
medicament for treating disease Y"

Claim construction

Swiss Type Fiction according to G5/83

"Use of compound X for the manufacture of a medicament
for the treatment of disease Y"

applicable for effective date up to 28 January 2011 (G5/83)

→ claim directed to industrial packaging of the substance with the
instructions for use;

→ claim limited by therapeutic indication

not any more applicable for effective date after 28 January 2011 (G2/08)

→ claim directed to process of manufacture of a medicament that is
merely suitable for the treatment of the disease

→ therapeutic indication not limiting
Claim construction – applicability Article 54(5) EPC

Claim:
Substance X...
... for use in the treatment of disease Y (purpose limited)
... for use in the treatment of disease Y (purpose limited)
... for use in the treatment of disease Y (for use in medicine)

Prior Art:
Substance X as a pesticide
Substance X as a medicament for treating disease Z

Effective date: 28.01.2011
Granted: 13.12.2006

European Patent Office
Claim construction – applicability G5/83

Claim:
Use of substance X for the manufacture of a medicament...
(...suitable) for the treatment of disease Y
...for the treatment of disease Y

Prior Art:
Substance X as a pesticide

Effective date: 28.01.2011
Granted: 13.12.2006

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Claim construction – applicability G5/83

Claim:
Use of substance X for the manufacture of a medicament...
(...suitable) for the treatment of disease Y
...for the treatment of disease Y

Prior Art:
Substance X as a medicament for treating disease Z

Effective date: 28.01.2011
Granted: 13.12.2006
Points for Discussion

- Claim construction
- “Mixed use”: therapeutic vs. non-therapeutic
- Novelty (further features)
- Clarity
- Absence of credible effect: Article 83 EPC vs. Article 56 EPC
- Late-filed evidence

Definition of the term “therapy” at the EPO

- Treatment (G5/83)
  - of a disease (pathological condition)
  - curative treatment
  - alleviation of the symptoms of pain and suffering (T144/83)

- Prevention of a pathology (prophylactic method)
  is included (T19/86; T290/86; T820/92)

- Even if the therapeutic aspect is not the main aspect, but cannot be clearly separated from the non-therapeutic aspect

- Pregnancy is not an illness (T74/93)

  Broad concept of "therapy"
Mixed use: 2 scenarios

Therapeutic effect and non-therapeutic effect...

...separable from each other | ...not separable from each other

medical use claim | yes  | medical use claim | yes
non medical use claim | yes  | non medical use claim | no

Mixed use: effects separable

T144/83

Weight loss...

...for improving bodily appearance ➔ cosmetic
...for treating obesity ➔ therapeutic
## Mixed use: effects separable

### T453/95 ; T1711/08

Hair growth enhancement...

- ...for reducing normal daily hair loss ➔ cosmetic
- ...for treating pathologic forms of alopecia ➔ therapeutic

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## Mixed use: effects separable

### T36/83

Acne treatment...

- ...based on comedolytic effect (skin cleansing) ➔ cosmetic
- ...based on antibacterial effect ➔ therapeutic
Mixed use: effects not separable

T290/86

Plaque removal...

...inevitably preventive treatment of caries ➔ therapeutic

Mixed use: effects not separable

T1077/93 ; T1649/06

UV Radiation Absorber

Not simple filtration but interaction with the cellular mechanism in the epidermis inevitably preventing inflammation

➔ therapeutic
Mixed use: conclusions

- **Therapeutic effect?**
  - **NO**
    - Medical use claim format not applicable, purpose not distinctive (A54)
  - **YES**
    - **Therapeutic and non-therapeutic activities separable?**
      - **NO**
        - Medical use claim required (A53c)
      - **YES**
        - Non-medical use claim additionally possible
          - "Non-therapeutic use / method..."

Points for Discussion

- Claim construction
- “Mixed use”: therapeutic vs. non-therapeutic
- **Novelty (further features)**
  - Clarity
  - Absence of credible effect: Article 83 EPC vs. Article 56 EPC
  - Late-filed evidence
Novelty of medical uses – further features

- 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 (G2/08)

- The distinguishing features can be:
  - a new group of patients (T19/86, T233/96)
  - a new mode of administration (T51/93)
  - a new dosage (T56/97, T230/01)
  - a new clinical situation (T384/03, T1229/03)

Novelty of medical uses – mode of administration

- T51/93 : a specific mode of administration as the novelty-conferring feature

Treatment of male sexual disorders or infertility with human HCG
Prior art: intramuscular administration
Application: subcutaneous administration

Advantages:
- less nerve lesions
- self administration possible
- as effective as intramuscular administration

→ Mode of administration is important for medical treatment
→ It can serve as distinguishing feature over prior art
Novelty of medical uses – patients

- **T 233/96**: a specific patient group as the novelty-conferring feature

Conditions defined in T 233/96:

- No overlap of patient group with group treated in prior art
- Physiological or pathological status of the selected group as distinguishing feature
- No arbitrary selection: link between envisaged therapeutic use and physiological or pathological status of patient group

Novelty of medical uses – dosage

**G2/08**

- The patenting is **not excluded** where a dosage regime is the only feature claimed which is not comprised in the state of the art.

- *The [dosage regimen] must not only be verbally different from the prior art but must also reflect a different technical teaching*

→ It must result in a different treatment by therapy of the same illness
Novelty of medical uses – dosage: the taxol case

“Use of taxol ... for the manufacture of a medicament for the administration of from 135mg/m2 up to 175mg/m2 taxol over a period of about 3 hours or less for treating cancer”

- Prior art:
  - standard therapy 24 hour infusion
  - side effect: neutropenia
  - study on 6 hour infusion: no anticancer effect

- Patent application: comparative data showed anticancer effect of 3 hour infusion and reduced incidence of neutropenia
  - additional advantage: no 24 hour hospitalisation needed

3 hour infusion is now standard therapy

... but patent revoked in Europe because inventor disclosed invention at a conference before the priority date...

Novelty of medical uses – new clinical situation

<table>
<thead>
<tr>
<th>T384/03 Facts</th>
<th>T1229/03 Facts</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Prior art</strong></td>
<td><strong>Prior art</strong></td>
</tr>
<tr>
<td>- carbonic anhydrase inhibitor (CAI) for treating</td>
<td>- estrogen compound for treating</td>
</tr>
<tr>
<td>- glaucoma</td>
<td>- neurodegenerative diseases</td>
</tr>
<tr>
<td>- by ↓ intraocular pressure (IOP ↓)</td>
<td>- by neurotrophism</td>
</tr>
<tr>
<td><strong>Claim</strong></td>
<td><strong>Claim</strong></td>
</tr>
<tr>
<td>- same compound for treating</td>
<td>- same compound for treating</td>
</tr>
<tr>
<td>- same disease</td>
<td>- same disease</td>
</tr>
<tr>
<td>- new effect / mechanism by ↑ ocular blood flow (OBF ↑)</td>
<td>- new effect / mechanism by neuroprotection</td>
</tr>
</tbody>
</table>
Novelty of medical uses – new clinical situation

T384/03 Decision

CAI ↓
OBF ↑
IOP ↓
Glaucoma ↓

➔ New mechanism (OBF ↑) not independent from known mechanism (IOP ↓);
➔ No new clinical situation;

T1229/03 Decision

Estrogen compound ↓
Neuroprotection (prevent)
Neurotrophism (repair)
Neurodegeneration ↓

➔ New mechanism (neuroprotection) independent from known mechanism (neurotrophism);
➔ New clinical situation (Art 54 EPC)

Novelty of medical uses – mechanism of action

Use of known substance for a known medical use:

Discovery of a technical effect (e.g. mechanism of action) in relation to the known use

➔ does not confer novelty *

(T254/93; T892/94; T189/95; T486/01)

* if the new technical effect leaves the known use unaffected
Novelty of medical uses – mechanism of action

- **T 254/93:**
  - Invention: use of a retinoid in the preparation of a topically administrable medicament for use in the prevention of corticosteroid-induced skin atrophy
  - Prior art: compositions comprising a retinoid and a corticosteroid
  - Advantages: the use of retinoid eliminates the usual side-effects of corticoid therapy
  - Conclusion: the *discovery* of the *mechanism of action* of known compound used for a known therapeutic application does not define a novel invention

Novelty of medical uses – mechanism of action

- Novel mechanism of action *not distinctive per se*
  - Mechanism is distinctive, if it results in a *novel clinical situation* (in the form of a new patient population or another dose)
  - Not decisive whether new effect inherently took place, but whether new effect implies a different situation where the use is to occur (confirmation of principles of G2/88 on second non-medical use)
Points for Discussion

- Claim construction
- “Mixed use”: therapeutic vs. non-therapeutic
- Novelty (further features)

Clarity

- Absence of credible effect: Article 83 EPC vs. Article 56 EPC
- Late-filed evidence

Clarity of second medical use claims

Clear and complete further medical use requires definition of:

- illness or disease to be treated or ailment to be cured;
- nature of the therapeutic compound used for treating or curing the disease; and
- subject to be treated
  (often implicitly defined as: a subject suffering from the disease or ailment)

(decision T4/98)
Clarity of second medical use claims - No

- **T241/95**:

  "(R)-fluoxetine for treating a condition which can be improved or prevented by selective occupation of the 5-HTIC receptor"

  - Scope of claim embraces undefined number of conditions all allegedly capable of being treated by the selective occupation of 5HTIC receptor
  
  - 2-fold activity of fluoxetine:
    (i) selective occupation of the 5-HTIC receptor
    (ii) serotonin-uptake inhibition
  
  - Requirements of Article 84 EPC are not met

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Clarity of second medical use claims - No

- **T1048/98**:

  "Compound for treating conditions related to vasodilatation"

  - Not clear whether vasodilatation is increased or decreased
  
  - Pharmacological effect on calibre of blood vessels not in itself a therapeutic application
  
  - Undefined number of diseases which might be related to this pharmacological effect
  
  - Practical application in the form of a defined treatment of a specified pathological condition essential technical feature for purpose of clarity
Clarity of second medical use claims - Yes

- T 836/01:
  "IF beta2 for influencing tumour cell growth and differentiation"
  - Derivable that claim is directed to treatment of tumour and cancer

- T 1918/06:
  "2Alpha4beta1 antibody for suppressing immune response"
  - Indication considered as clear

Points for Discussion

- Claim construction
- "Mixed use": therapeutic vs. non-therapeutic
- Novelty (further features)
- Clarity
- Absence of credible effect: A.83 EPC vs A.56 EPC
- Late-filed evidence
Absence of credible effect

**G1/03 (reasons 2.5.2)**
- Effect expressed in claim → Lack of sufficient disclosure
- Effect not expressed in claim → Problem of inventive step

**T939/92 (reasons 2.4 to 2.6)**
Alleged technical effect not achieved by all claimed compounds
→ Rather an issue of inventive step than of support

**CL I.D.4.4**
Alleged technical effect not credibly shown within whole area claimed
→ Technical problem to be reformulated in a less ambitious way

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Absence of credible effect - product

- **T 1319/10:**
  - "A synergistic microbicidal composition comprising A and B"

- Examining Division:
  - D1: synergistic microbicide comprising A’ and B
  - Problem: alternative synergistic microbicidal composition
  - Claimed solution obvious from D2 → inventive step NO

- Board of Appeal:
  - Doubts as to credibility of synergy over entire scope of claim
  - Synergy expressed as functional feature of claimed product
  - Synergy part of claimed solution, not of technical problem
  - Whether or not synergy is obtained is a matter of A83
  - Remittal to 1st instance for a decision under A83
Absence of credible effect - conclusion

Alleged effect not credibly shown

Effect part of claimed solution

Yes

Objection under A83

No

Objection under A56
Complete problem-solution approach
Reformulation of technical problem

Points for Discussion

- Claim construction
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- Late-filed evidence
Late-filed evidence

- Absence of experimental data at the date of filing is not enough to disregard later filed evidence (see also T578/06)

- Late-filed evidence must be taken into consideration as a back-up of evidence already available from the application or the prior art

- Disregard of late-filed evidence limited to 2 scenarios:
  (i) newly demonstrated effect inconsistent with teaching as filed
  (ii) substantiated doubts concerning plausibility of the effect (e.g. based on diverging teaching of the prior art)

Novelty of medical uses – further features
Köszönöm a figyelmet!

Van kérdés?

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