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## First and Second Medical Use

An Overview of EPO Case Law and Practice



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### 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  $\equiv$  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 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 such 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
<b>1st medical use:</b>	<b>"Substance X for use in medicine"</b>

## 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**"

## 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

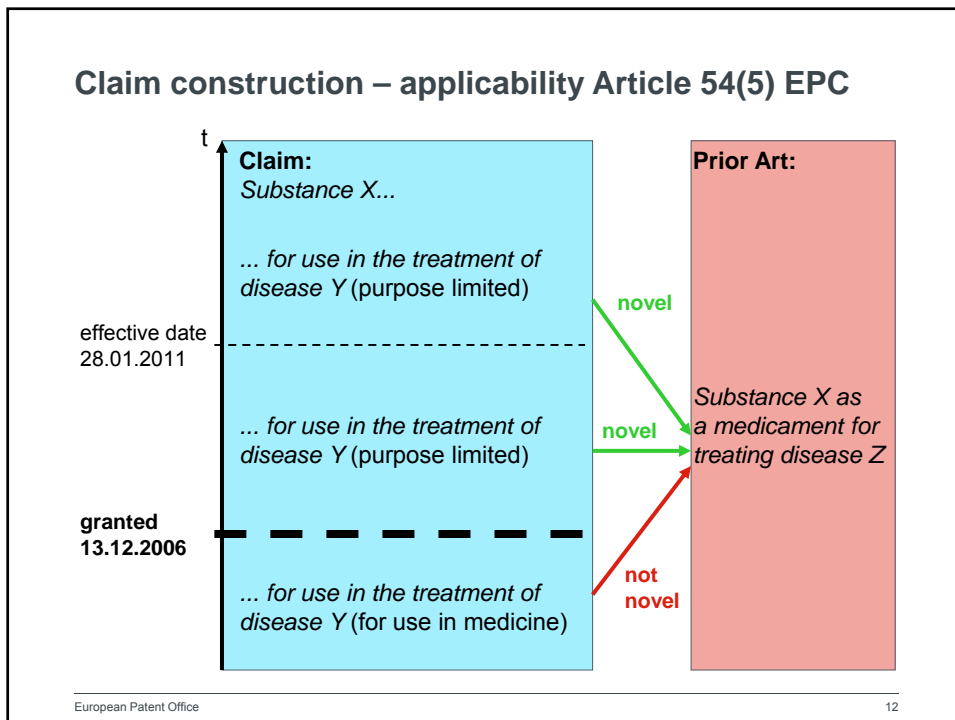
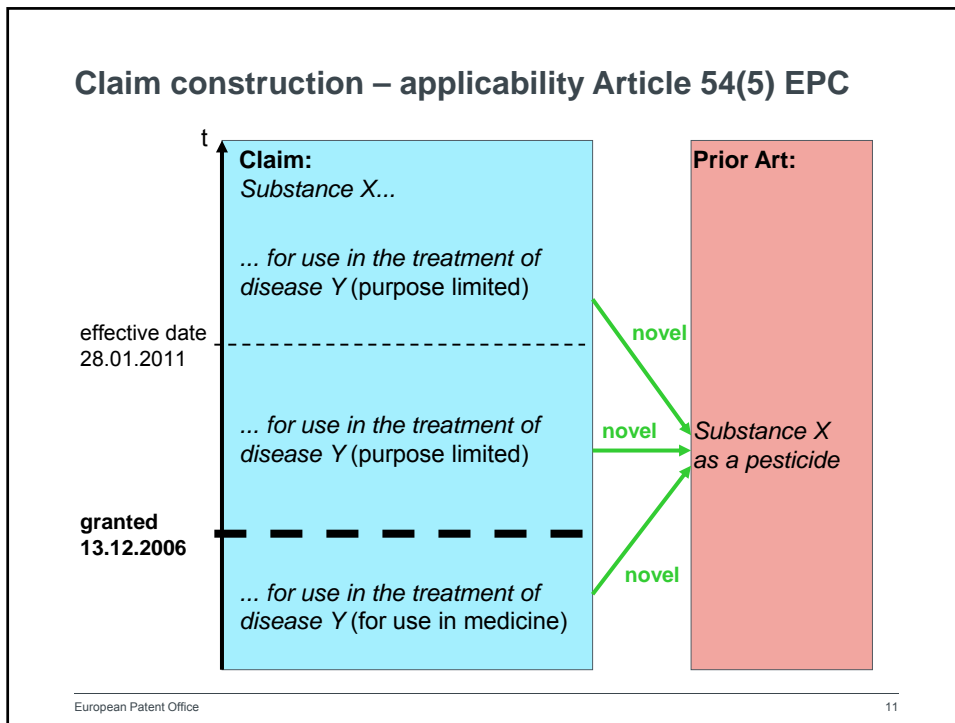
*"Use of compound X for the **manufacture of a medicament** for the treatment of disease Y"*

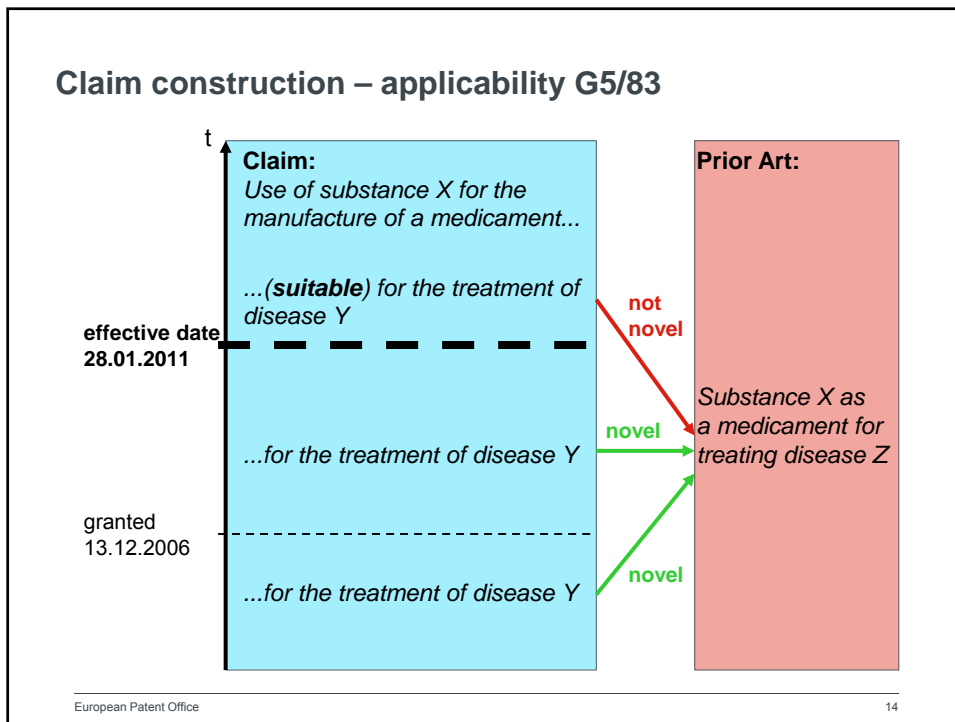
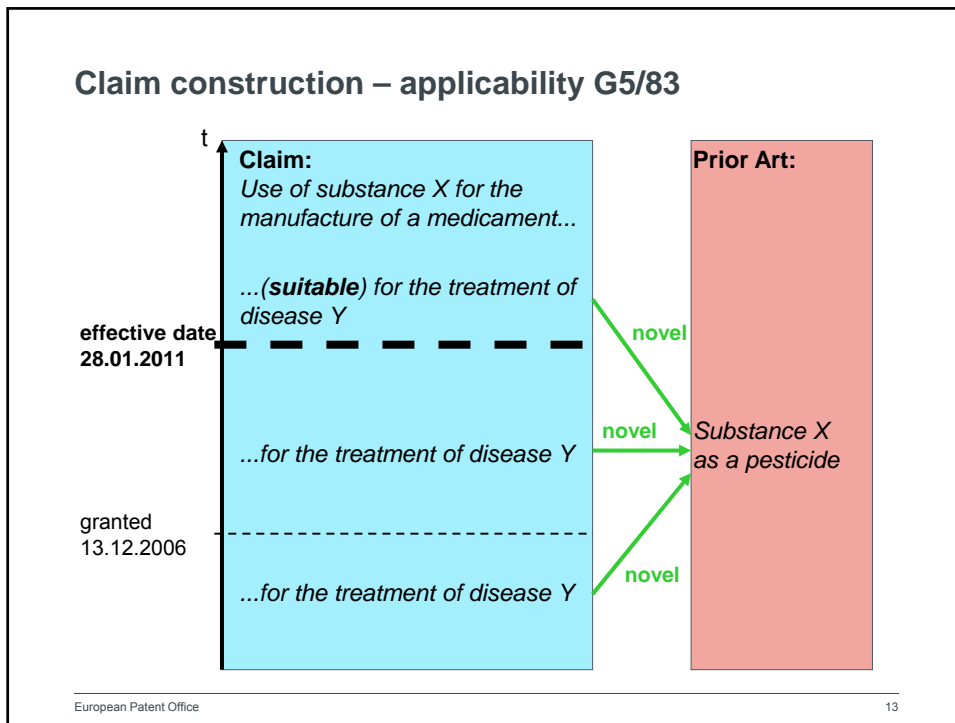
applicable for effective date up to **28 January 2011 (G5/83)**

- 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**





## 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

medical use claim    **yes**  
non medical use claim    **yes**

...**not separable** from each other

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

**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**

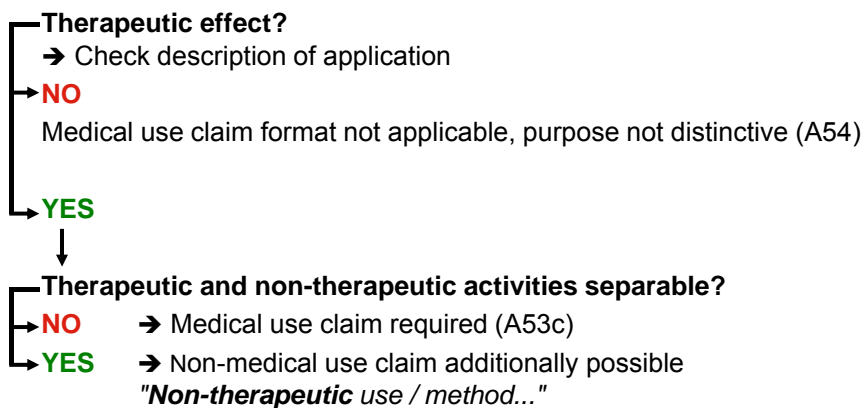
**T1077/93 ; T1649/06**

**UV Radiation Absorber**

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

→therapeutic

### Mixed use: conclusions



### 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/m<sup>2</sup> up to 175mg/m<sup>2</sup> 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...*

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## Novelty of medical uses – new clinical situation

### T384/03 Facts

#### **Prior art**

- carbonic anhydrase inhibitor (CAI) for treating
- glaucoma
- by ↓ intraocular pressure (IOP ↓)

#### **Claim**

- same compound for treating
- same disease
- new effect / mechanism  
by ↑ ocular blood flow (OBF ↑)

### T1229/03 Facts

#### **Prior art**

- estrogen compound for treating
- neurodegenerative diseases
- by neurotrophism

#### **Claim**

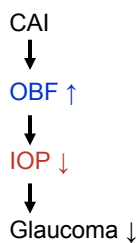
- same compound for treating
- same disease
- new effect / mechanism  
by neuroprotection

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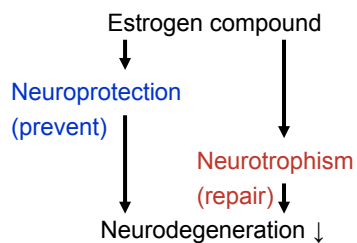
## Novelty of medical uses – new clinical situation

### T384/03 Decision



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

### T1229/03 Decision



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

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## 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

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## 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

### 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

## Absence of credible effect - product

### ▪ T 1319/10 :

*"A synergistic microbicial composition comprising A and B"*

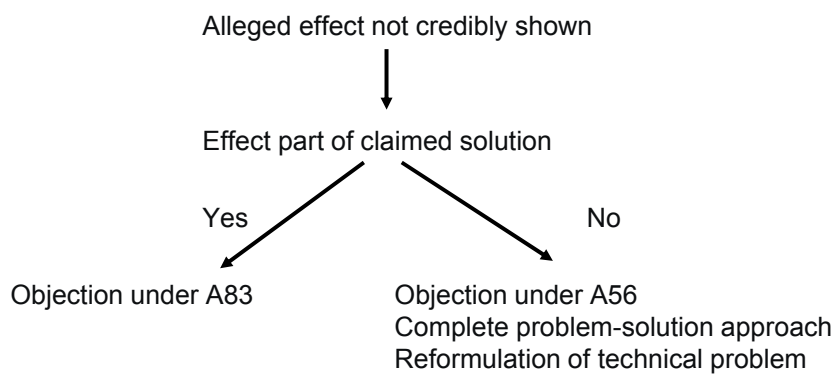
#### ▪ Examining Division:

- D1: synergistic microbicide comprising A' and B
- Problem: alternative synergistic microbicial 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



## Points for Discussion

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- **Late-filed evidence**

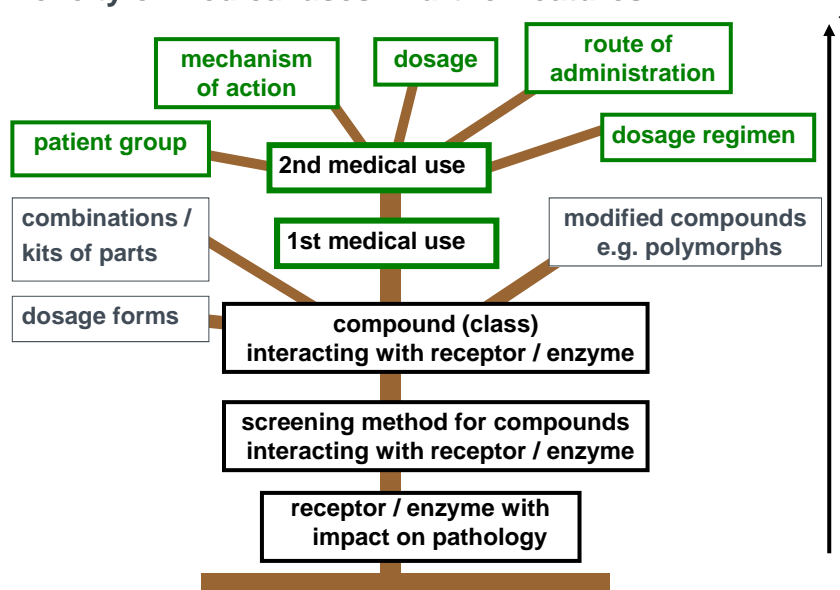
## Late-filed evidence

- 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)

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## Novelty of medical uses – further features



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Köszönöm a figyelmet!

Van kérdés?

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