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Patenting of Pharmaceutical Inventions at the EPO





Dr. Dieter Tzschoppe
Director Pure and Applied Organic Chemistry
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Legal framework - Patentability (Art. 52(1) EPC)

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.

Article 53 EPC – Exceptions to patentability

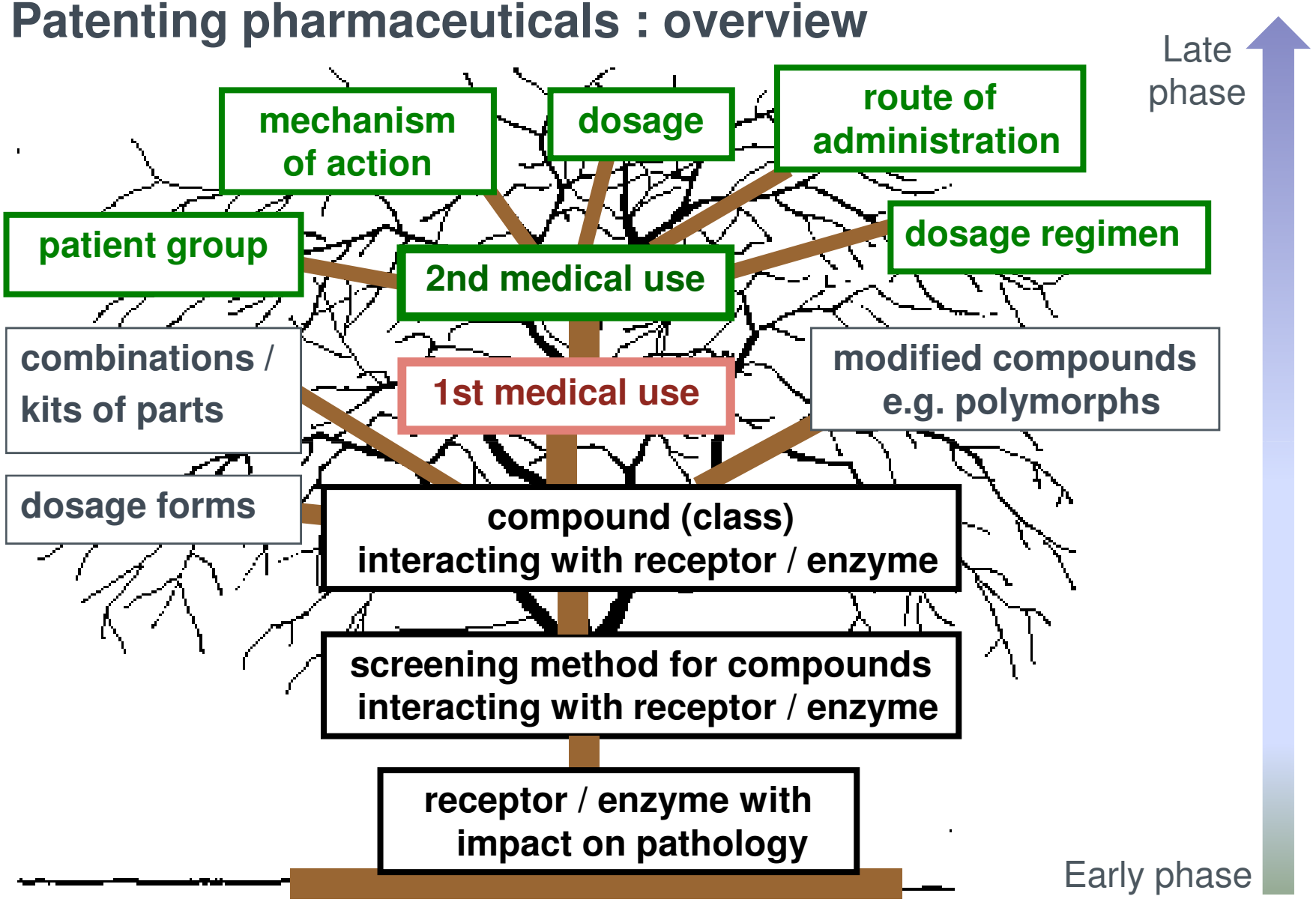
European patents shall **not** be granted in respect of:

a) Inventions the commercial exploitation of which would be contrary to "ordre public" or morality; such exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States;

b) Plant or animal varieties or essentially biological processes for the production of plants or animals; this provision shall not apply to microbiological processes or the products thereof;

c) Methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practiced 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.

Patenting pharmaceuticals : overview



"Primary/Secondary patents" distinction (1)

- Not terms of art in European patent law
- Promoting inventions building on earlier innovation one of the aims of patent system
  - Mandatory 18-month publication of applications
  - Experimental use exception
- Such "follow-on" inventions are also made by third parties, not just by the inventors of earlier invention

"Primary/Secondary patents" distinction (2)

- Fundamental principles under the EPC:
  - All applications treated equally and fairly
  - Subject only to patentability requirements of the EPC
  - Subjective elements are irrelevant (commercial potential of invention; its value to society...)

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.

Second medical use claims : allowable format

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.

In pending applications also the Swiss-type format:

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

A54(5) EPC - 2nd and Further Medical Use

Product: *"Substance X„*

↑ not **novel over**

Non-medical use: *"Substance X* ***for use in*** *agriculture"*

↑ **novel over**

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

↑ **novel over**

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

↑ **novel over**

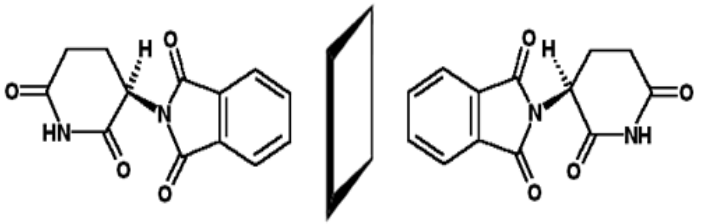
Further medical use: *"Substance X* ***for use in*** *treating disease Z"*

Second medical use – Rationale for it

- Development from discovery to market approval for entirely new drugs extremely costly
- Screening of known drugs for new diseases faster than entirely new developments
- Patent as reward for investing in research and development also for further medical uses

Second medical use – Example Thalidomid

- First approved as hypnotic
- One enantiomer responsible for phocomelia (malformations)
- further uses are treatment of leprosy and cancer



R-Thalidomid
(Schlafmittel)

S-Thalidomid
(teratogen: löst schwere Miss-bildungen bei Embryos aus)



FDA Clears Thalidomide For Leprosy

WARREN, NJ -- July 16, 1998 – The United States Food and Drug Administration has granted marketing clearance to Celgene Corp.'s Thalomid(TM) (thalidomide) for the treatment of erythema nodosum leprosum (ENL), a severe and debilitating condition associated with leprosy.

Celgene licensed rights to thalidomide from The Rockefeller University in 1992 and began developing the drug for a range of potential indications. These include AIDS related, dermatological and cancer related conditions.

Second medical use – further examples

- Sildenafil
  - – - pulmonary arterial hypertension
  - – erectile dysfunction
- Duloxetine
  - – depression
  - – detrusor instability
- Buprenorphine
  - – moderate pain in low dosage
  - – opioid addictions in high dosage
- Zoledronic acid
  - – tumour induced hypercalcemia
  - – osteoporosis
- Acetylsalicylic acid
  - – anti-inflammatory
  - – prevents heart attacks, stroke at low doses

Further 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)
- a new clinical situation (T384/03, T1229/03)
- a new dosage regime

Second and further medical uses – T19/86 (1987)

2nd medical use with same compound for same treatment as known, but different group of patients?



T19/86: Pigs II: yes

Different immunologic population treated (prophylactic)

Conclusions:

- "therapy" in the sense it is used in Art. 52(4) includes both curative and prophylactic treatment
- Concept of patentability of second medical use in accordance with G5/83 should be construed broadly
- Medical indication is incomplete if the subject to be treated is not identified

Second and further medical uses – Patient group – T233/96

Concept of T19/86 never objected by other boards but confirmed by numerous decisions.

Specific conditions developed in T233/96

1) Group must be distinguishable with respect to physiological or pathological status

2) Group may not overlap with previously treated group

3) Group may not be selected arbitrarly – relationship between physiological or pathological status and therapeutic effect must exist

Second and further medical uses – T290/86 (1990)

Second medical use with same compound for same therapeutic purpose but based on different technical effect?

Application:
Lanthanum salts for cleaning plaque from human teeth

Prior art:
Lanthanum salts for depressing solubility of tooth enamel in acids

Inhibition of tooth decay



T290/86:
When prior art and claimed invention are concerned with similar treatment for the same therapeutic purpose, then claimed invention represents further medical indication within G5/83 if it is based on different (novel and inventive) technical effect

Second and further medical uses – T254/93 (1997)

"Explanation" of technical effect

"Use of a retinoid in the preparation of a topically administrable medicament for use in the prevention of corticosteroid-induced skin atrophy"

<u>Prior art</u>: corticoid + retinoid for treating skin diseases



Board: claimed use not novel

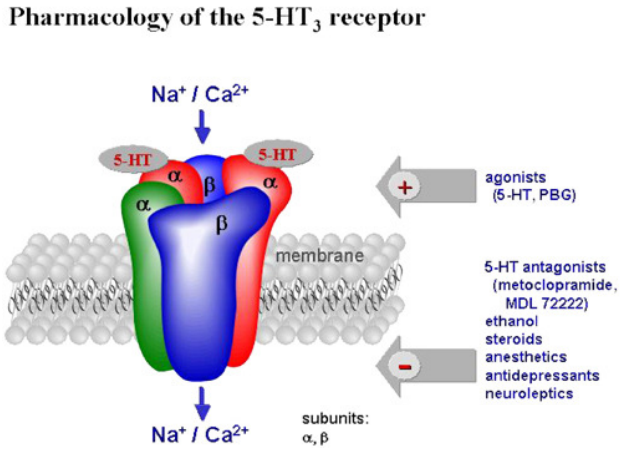
Medical practioner cannot overlook symptoms of skin atrophy

Medical practioner would have continued prior art treatment with **full understanding** that retinoid prevents skin atrophy

Second and further medical uses – T241/95 (2000)

Functional definition of disease - receptor occupation

"Use of (R)-fluoxetine (...) for the preparation of a medicament or treating a mammal suffering (...) from a condition which can be improved by selective occupation of the 5-HTIC receptor."

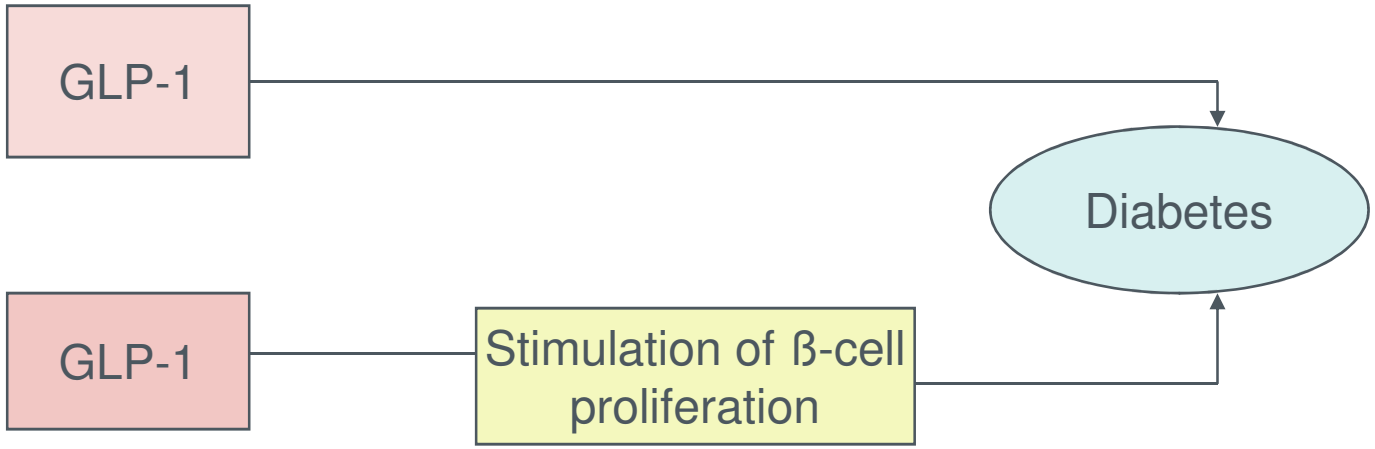


"selective occupation of a receptor – though indisputably a pharmacological effect, is NOT a therapeutic application"
Only a practical application in the form of a defined, real treatment of any pathological condition can be considered an invention eligible for patent protection.

Functional definition "clear" only if the link between receptor and disease results EITHER from instructions in the description such as experimental tests or any testable criteria OR the link is part of the common general knowledge

Second and further medical uses – Technical effect in body

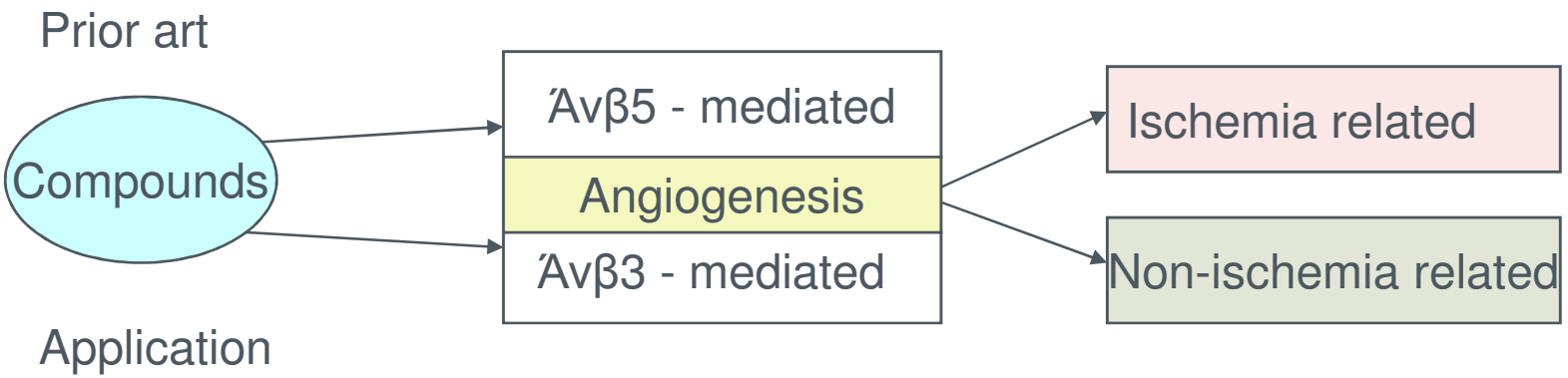
T 406/06 (2008)



Technical effect does not lead to new therapeutic use

Second and further medical uses – Technical effect in body

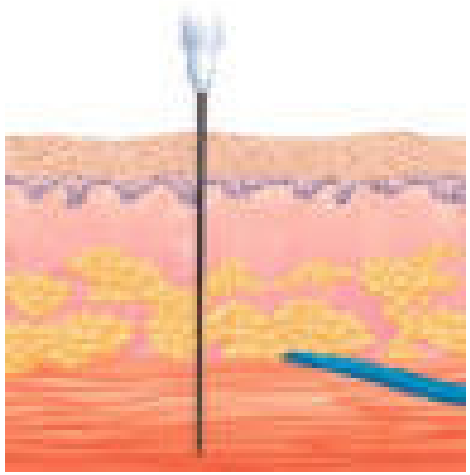
T1127/05 (2008)



New area of therapeutic treatment

Second medical use – T51/93 - mode of administration (1994)

Second medical use with same compound for same illness but different mode of administration?



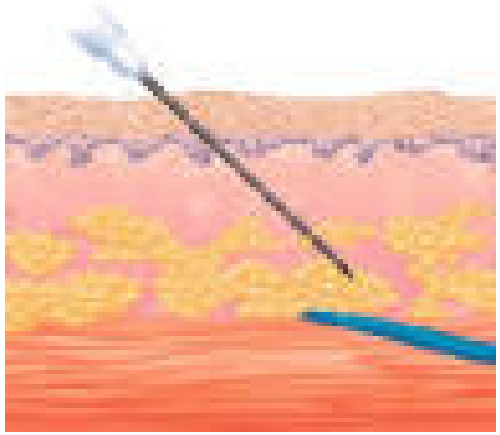
T51/93: yes (with reference to T19/86 and 290/86)

Use of human HCG for manufacture of a non-depot medicament for use in the treatment by subcutaneous administration of infertility or male sexual disorders.

Known: intramuscular administration for same disease

Reasons:

mode of administration is critical factor for medical treatment, no **a priori** bar to rely on this difference when distinguishing over prior art



self administration possible
reduction of nerve lesions
data show equal effectiveness vs prejudice in textbooks

Second medical use - Dosage regime- 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 as a means for treating cancer and simultaneously reducing neutropenia.



Prior art:
Standard therapy 24 hours infusion
Side effect: Neutropenia
6 hour infusion (study): no anticancer effect

Patent application:
Comparative data show 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 conference before priority date

Second medical use claims

- The exception of Art. 54(5) EPC is also applicable to products for use in an **in vivo diagnostic 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 tumor cells.

Conclusion

- Second or further medical use claims allow the protection of any **"specific use"** in a method referred to in Art. 53(c) EPC provided that such use is not comprised in the state of the art (Art. 54(5) EPC)

- The **"specific use"** is **not** limited to a new disease...

  ...can be a new group of patients, mode or route of administration, a new clinical situation or a dosage regimen.

  → but new **technical teaching** different from the teachings in the prior art

- **No Swiss-type format** in future patent applications (G2/08)
  - Applications with a filing date or with earliest priority date of **29.01.2011** or later.
  - Divisional : relevant date = filing or priority date of the parent application.

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Thank you for your attention!

