

ESSENTIAL ASPECTS TO BE CONSIDERED WHEN ASSESSING NOVELTY AND INVENTIVE STEP

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ESSENTIAL ASPECTS

- What is (and was is not) an invention, Art. 52(1),(2) EPC
- Exception to patentability, Art. 53(c) EPC
- Novelty, Art. 54 (1), (2) EPC
- 1st medical use claims, Art. 54(4) EPC
- 2nd and further medical use claims, Art. 54(5) EPC
- New therapeutic applications – what confers novelty to a 2nd medical use claim
- Inventive Step, Art. 56 EPC

WHAT IS AN INVENTION – ART. 52(1) EPC

Art 52(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.

Physical entity		Activity	
Device / apparatus	Product	Process / method	Use
Object X	Compound X	Process for purpose Y comprising step Z	Use of substance X for purpose Y

WHAT IS NOT AN INVENTION – ART. 52(2) EPC

Art 52(2): The following, in particular, **shall not be regarded as inventions**:

- a) discoveries, scientific theories, mathematical methods;
- b) aesthetic creations;
- c) schemes, rules and methods for performing mental acts, playing games or doing business, and programs for computers;
- d) presentations of information.

GL G-II, 3 and sub-sections

EXCEPTIONS TO PATENTABILITY – ART. 53 EPC

European patents shall not be granted in respect of:

- (a) inventions contrary to "ordre public" or morality;
- (b) plant or animal varieties and processes for their production;
- (c) methods of **surgery, therapy and diagnostic** practised on the human or animal body.

GL G-II, 4 and sub-sections

EXCEPTIONS TO PATENTABILITY – ART. 53(C) EPC (1/2)

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;



Ensures that doctors and veterinarians can practice medicine without being inhibited by patent rights.

NOVELTY (ART. 54 EPC)

- (1) An invention shall be considered to be new if it does not form part of the state of the art
- (2) The state of the art shall be held to comprise everything made available to the **public** by means of a written or oral description, by use or in any other way, before the date of filing of the European patent application
- (3) Additionally, the content of European patent applications as filed, the dates of filing of which are prior to the date referred to in paragraph 2 and which were published on or after that date, shall be considered as comprised in the state of the art

NOVELTY (ART. 54 EPC)

- Definition of the "public"
 - If the disclosure is subject to a confidentiality agreement, then it is not public
 - If there is no condition of confidentiality, the public has access
- Beware of disclosing your invention too early in:
 - Academic papers
 - Investor relation presentations
 - Medical trials data publicly available
 - Earlier application(s)!

FIRST MEDICAL USE CLAIM – ART. 54(4) EPC

(4) 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**.

EXCEPTIONS TO PATENTABILITY – ART. 53(C) EPC (2/2)

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.

GL G-II, 4.2.1 and subsections

SECOND AND FURTHER MEDICAL USE CLAIM – ART. 54(5) EPC

(4) Paragraphs 2 and 3 shall 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.

WORDING OF MEDICAL USE CLAIMS: DOS




■ 1st medical use

- ✓ Compound/composition X **for use** as a medicament.
- ✓ Compound/composition X **for use** in therapy.

■ 2nd medical use

- ✓ Compound/composition X **for use** in (a method for) the treatment of cancer.
- ✓ Compound/composition X **for use** in a method for treating cancer.
- ✓ Compound/composition X **for use** as an anti-inflammatory agent.

FIRST, SECOND AND FURTHER MEDICAL USE CLAIM ART. 54(4) AND (5) EPC

Claim type	
Product	Compound X  New over (Art. 54(4))
1 st medical use claim	Compound X for use in medicine  New over (Art. 54(5))
2 nd medical use claim	Compound X for use in treating disease Y  New over (Art. 54(5))
Further medical use claim	Compound x for use in treating disease Z

G-VI, 7.1 and sub-sections

WORDING OF MEDICAL USE CLAIMS: DON'TS

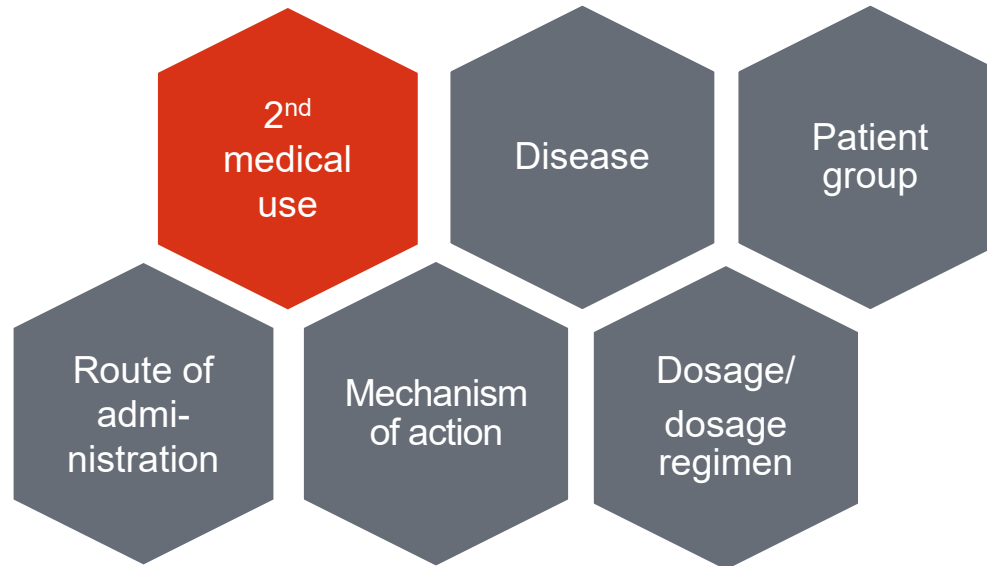
■ Impro wordings

- ⊗ Compound/composition X as the treatment of cancer.
- ⊗ Pharmaceutical composition comprising X for topical treatment.
- ⊗ Anti-bacterial composition comprising X.

■ Excluded from patentability

- ⊗ Method of treating disease Y by using substance X.
- ⊗ Use of substance X for treating disease Y.

NEW THERAPEUTIC APPLICATIONS



G-VI, 7.1.2

NEW DISEASE

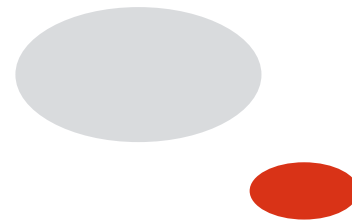
*Aspirin for use in the prevention of **cancer**.*

Aspirin is known for use in the treatment of inflammatory diseases.

The claim is **new** (Art. 54(5) EPC).

NEW PATIENT GROUP

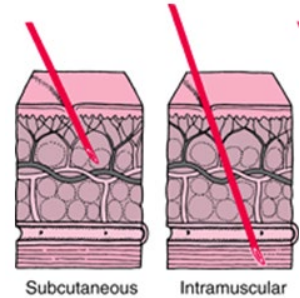
- Patient groups distinguishable by their physiological or pathological status
- Parallel groups,
e.g. non-haemophilic novel over haemophilic patients



NEW MODE OF ADMINISTRATION

"... HCG for treating infertility *by subcutaneous administration*"

- ▶ **subcutaneous** novel over **intramuscular** administration
- ▶ difference in mode of administration distinctive over prior art



NEW DOSAGE

*"compound X for use in treating cancer with a **daily dose of 30-60mg**"*

- ▶ **dosage novel over**
 - **No dose** disclosed in the prior art
 - **Lower dose** disclosed in the prior art, e.g. 10-20mg
 - **Higher dose** disclosed in the prior art, e.g. 70-100mg
 - **A broader dose** (more generic) disclosed in the prior art, e.g. 1-1000mg (specific selection of a dose)

- ▶ **dosage feature** suitable for delimitation from prior art

NEW DOSAGE REGIMEN

*"Risedronate for use in the treatment of osteoporosis wherein the risedronate is **administered every month during the first three days of the month**"*

- ▶ Novel over prior art disclosing continuous daily administration
- ▶ A **new technical effect** caused by said dosage regimen shall be considered when examining inventive step under Art.56 EPC

NEW MECHANISM OF ACTION

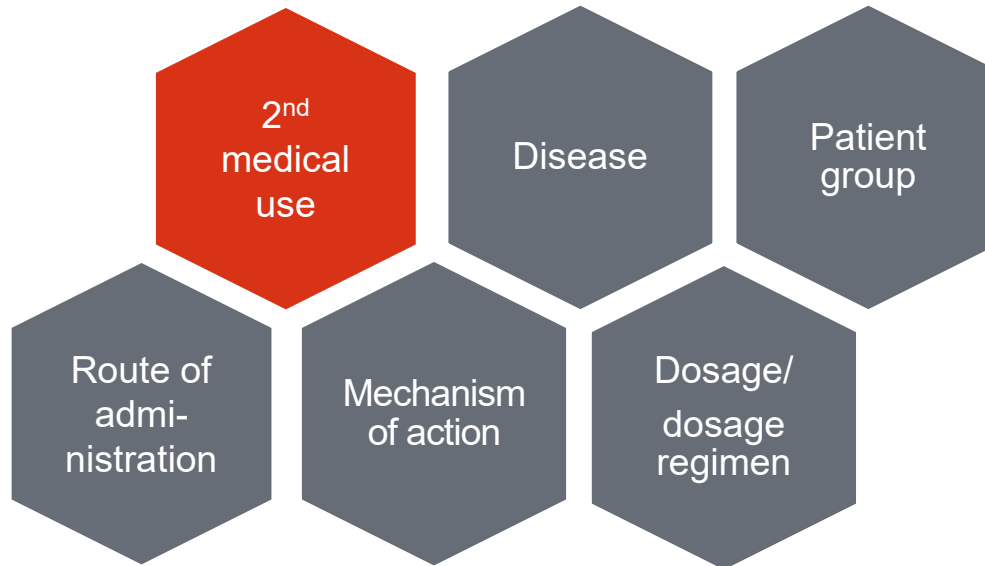
- Purely functional definition of therapeutic indication is only clear, if specific conditions are immediately apparent to skilled person
- New mechanism of action is **not *per se* distinctive**
- The mechanism is distinctive, if it results in a **novel clinical situation**

MEDICAL USE CLAIMS IN THE GUIDELINES

- Part F The European Patent Application
 - F-IV.3 Kinds of claims

- Part G Patentability
 - **G-II Inventions**
 - **G-II, 3 List of exclusions**
 - **G-II, 4 Exceptions to patentability**
 - **G-VI Novelty**
 - **G-VI, 7.1 First or further medical use of known products**

NEW THERAPEUTIC APPLICATIONS, BUT IS IT INVENTIVE?



G-VI, 7.1.2

INVENTIVE STEP, ART 56 EPC

"An invention shall be considered as involving an inventive step if, having regard to the state of the art, it is not obvious to a person skilled in the art."

What is the contribution to the art?

INVENTIVE STEP, ART 56 EPC

Problem solution approach:

1. What is the closest prior art?
2. What is the difference between the claimed invention and the closest prior art?
3. What is the technical effect caused by this difference?
4. What is the technical problem corresponding to this effect?
5. Would it be obvious for the skilled person to arrive at the claimed invention?

GL-VII, 5