Europäisches Patentamt
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Patenting in the Medical - Pharmaceutical Field



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Patenting in the Medical - Pharmaceutical Field

- What is (not) an invention, Art. 52(1),(2) EPC
- Exception to patentability, Art. 53(c) EPC
- 1st and 2nd medical use claims, Art. 54(4),(5) EPC
- New therapeutic applications - what confers novelty to a 2nd medical use claim
- Personalized medicine
- Diagnostic methods
- Methods of surgery

What is an invention, Art. 52(1) EPC

Physical entities

Product – Apparatus

Compound/Composition

Activities

Process

Use

New	Art. 54 EPC
Inventive	Art. 56 EPC
Industrially Applicable	Art. 57 EPC

What is not an invention, Art. 52(2) EPC

The following, in particular, shall not be regarded as inventions :

a) discoveries, scientific theories, mathematical methods;

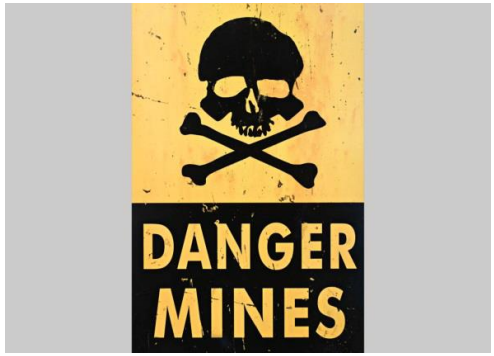
b) aesthetic creations;

c) schemes, rules and methods for performing mental acts, playing games or doing business, and programs for computers;

d) presentations of information.

Exceptions to patentability, Art. 53 EPC

Art. 53(a) EPC



Inventions against morality

Art. 53(b) EPC

Plant or animal varieties/ processes for their production

Art. 53(c) EPC

Methods of surgery, therapy, diagnostic on human/animal body

Article 53(c) 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 practiced on the human or animal body ...

Ensure that the doctors/veterinarians are **not inhibited** by patents **in the practice of medicine**
(G 5/83, G 1/04, G 1/07)

Article 53(c) 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 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.

➔ **Applicable** to chemical-biological entities such as compounds or cells

➔ **Not applicable** to medical devices

⟶ Article 54(4) and (5) EPC

1st and 2nd medical use claims, Art. 54(4),(5) 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.

(5) 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.

1st and 2nd medical use claims, Art. 54(4),(5) EPC

Compound X — product

↑ novel over

Compound X for use in medicine — 1st medical use, Art. 54(4)

↑ novel over

Compound X for use in treating disease Y — 2nd medical use, Art. 54(5)

↑ novel over

Compound X for use in treating disease Z — further medical use, Art. 54(5)

Wordings of medical use claims

1st medical use, Article 54(4) EPC :

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

2nd or further medical use, Article 54(5) EPC :

- ✓ 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 anti-inflammatory agent*

Wordings of medical use claims

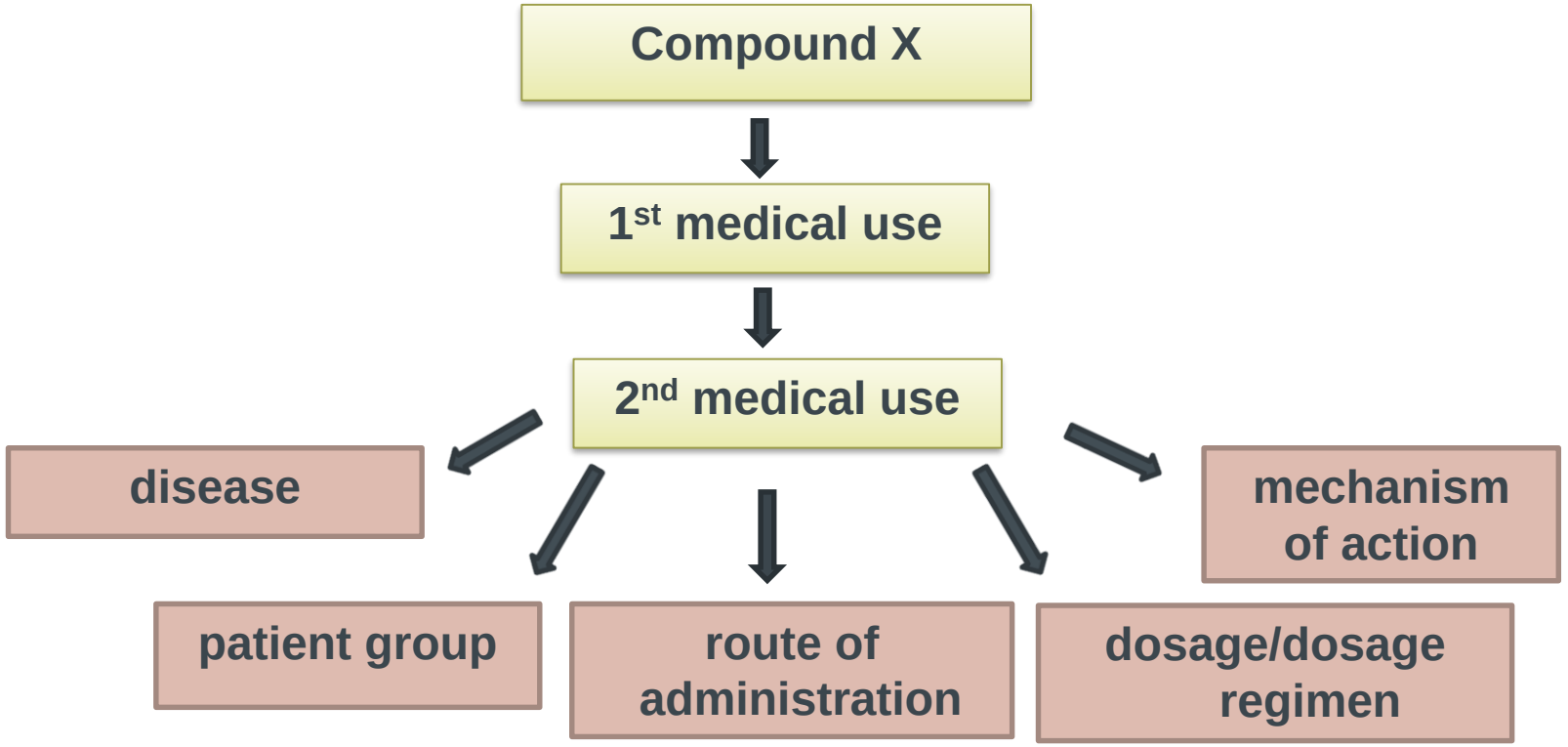
Non-acceptable wordings when compound X is known :

- ✗ *Compound/composition X for the treatment of cancer*
- ✗ *Pharmaceutical composition comprising X for topical treatment*
- ✗ *Anti-inflammatory composition comprising X*

Excluded from patentability, Article 53(c) EPC :

- ✗ *Method of treating disease Y by using substance X*
- ✗ *Use of substance X for treating disease Y*

New therapeutic applications

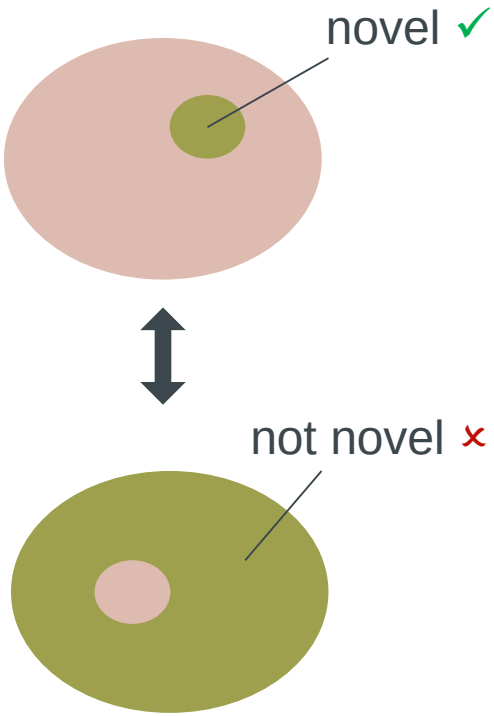


New therapeutic applications

Concept of Selection Inventions

"[...] a generic disclosure does not usually take away the novelty of any specific example falling within the terms of that disclosure,

but [...] a specific disclosure takes away the novelty of a generic claim embracing that disclosure."

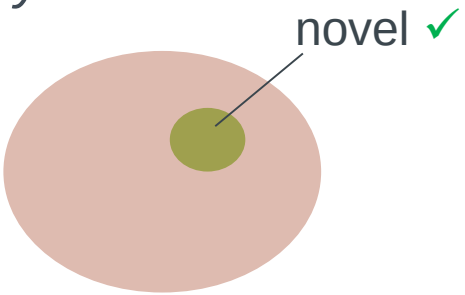


Guidelines G-VI.5

New therapeutic applications

Concept of Selection Inventions

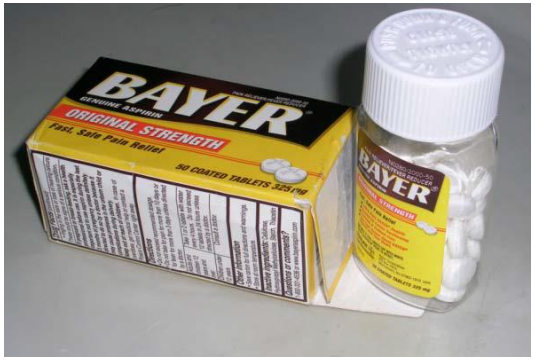
(-)-epigallocatechin for use in the treatment of obesity



prior art :

green tea extract for use in the treatment of obesity

New disease



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

➔ New disease since aspirin is known for use in the treatment of inflammatory diseases

New patient group

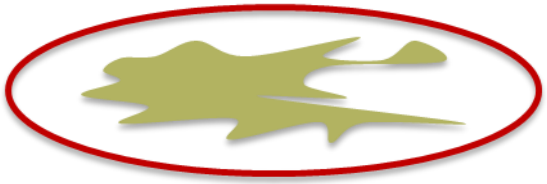
Novelty

- Patient groups distinguishable by their physiological or pathological status

- Parallel groups,
  e.g. non-hemophilic novel over hemophilic patients

New patient group 2

Subgroup of patients - Novelty



- Subgroup of patients,

e.g. poor TNF α-inhibitor responder sub-group

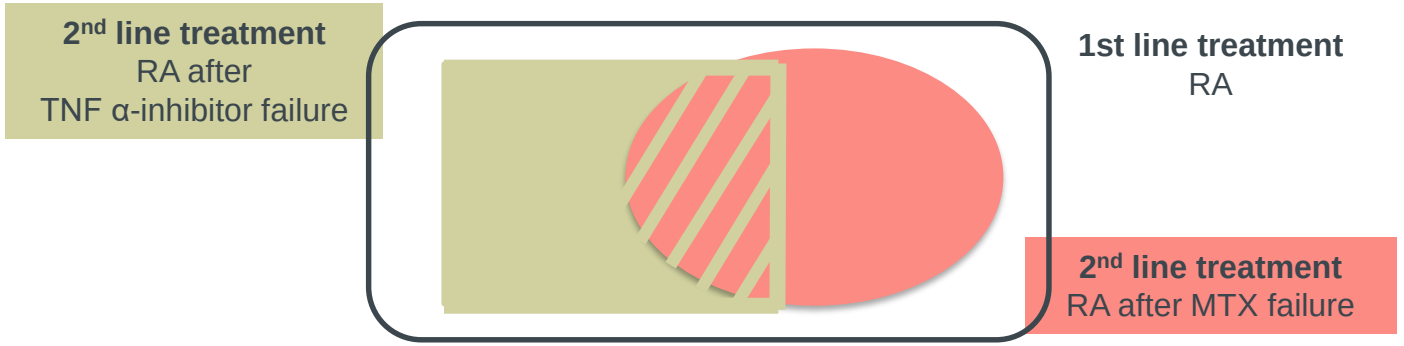
novel over previously treated more generic patient collective

New patient group 3

Overlapping Patient Group - Novelty

- Claim: *Rituximab... ...for treating rheumatoid arthritis (RA) ... ...a human who experiences an inadequate response to a TNF α-inhibitor*

- Prior Art: ✓ Rituximab for treating MTX refractory RA
  ✗ no reference to TNF α-inhibitor inadequate responders



? Selection of patient group novel ?

New patient group 4

Overlapping Patient Group - Novelty

- 30-40% of all RA patients TNF α-inhibitor inadequate responders
- TNF α-inhibitor inadequate responders distinguishable from the more generic RA patient group of the prior art by their physiological and pathological status (TNF α-inhibitor induced side effects, altered degree of RA)

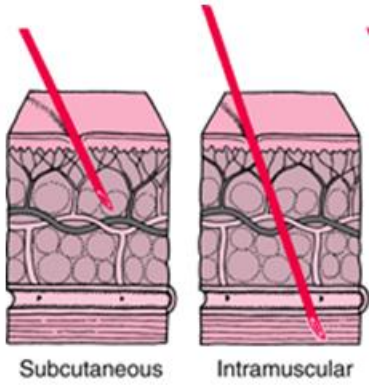
➔ **Selection of a patient-group suitable to confer novelty, if the claimed group is distinguishable from the known group by its physiological and pathological status** (T734/12)

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 - Clarity

Definition solely by mechanism of action

"*(R)-fluoxetine for treating a* ***condition which can be improved by selective occupation of the 5-HT1C receptor***"

How does the EPO deal with this kind of definition?

New mechanism of action – Clarity 2

Definition solely by mechanism of action

A clarity objection can be overcome by either:

➔ introducing into the claim a list of pathological conditions (diseases) cited in the application

➔ showing that the functionality can be verified using tests or procedures adequately specified in the description or known to the skilled person and which do not require undue experimentation, which allow the skilled person to recognise which additional condition/s fall within the functional definition

New mechanism of action - Novelty

Further Definition by Mechanism of action

- Claim: compound X for use in treating glaucoma...
  ...by increasing ocular blood flow (OBF ↑)
- Prior art: compound X for use in treating glaucoma,
  by lowering intraocular pressure (IOP ↓)

compound X ➡ OBF ↑ ➡ IOP ↓ ➡ Glaucoma ↓

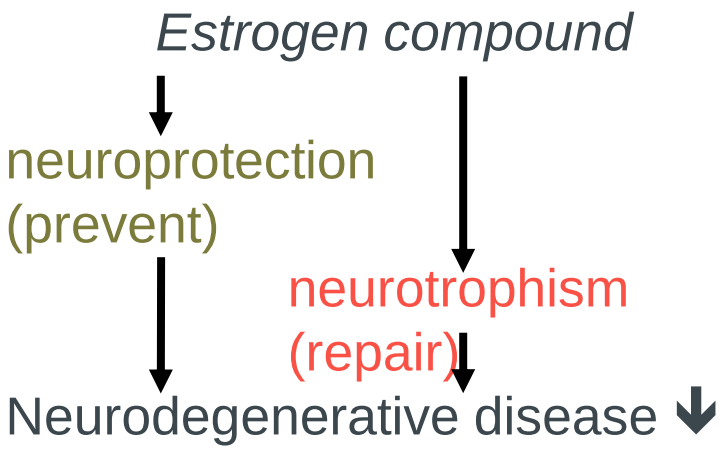
➔ New mechanism OBF↑ dependent from known mechanism IOP↓

➔ **No new** clinical situation (T384/03);

New mechanism of action – Novelty 2

Further Definition by Mechanism of action

- Claim: estrogen compound for use in treating neurodegenerative disease by neuroprotection
- *Prior art:* estrogen compound for use in treating neurodegenerative disease by neurotrophism



➔ New mechanism neuroprotection independent from known mechanism neurotrophism

➔ **New** clinical situation (T1229/03);

New mechanism of action

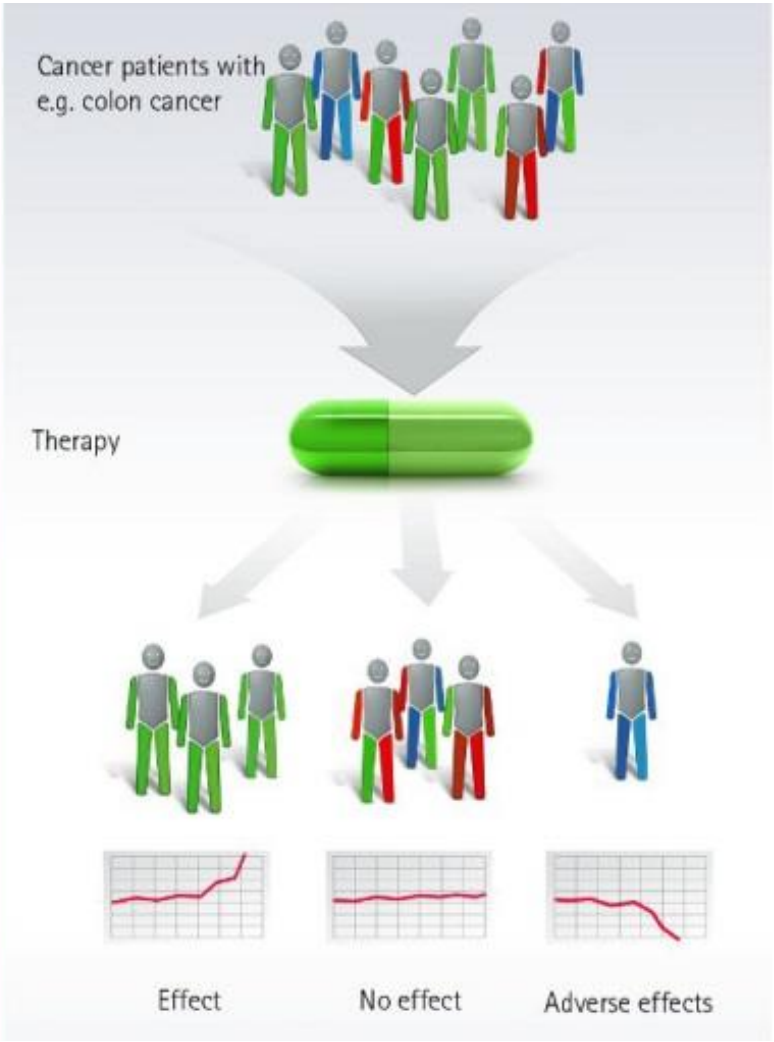
Summary:

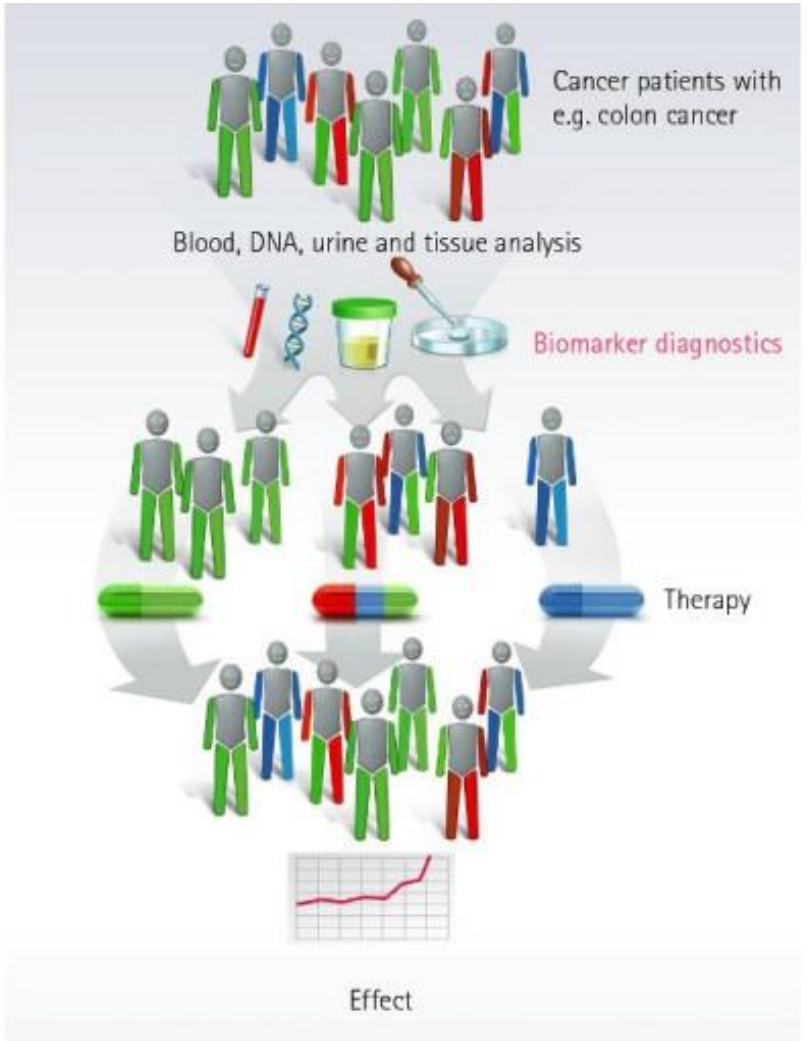
- Purely functional definition of therapeutic indication is only clear, if specific conditions are immediately apparent to skilled person

- Novel mechanism of action is **not *per se* distinctive**

- The mechanism is distinctive, if it results in a **novel clinical situation**

Personalised medicine: tailored treatments





Personalised medicine: tailored treatments

- **Goals:**
  - The right treatment
  - At the right dose
  - For the right patient
  - At the right time
  - For the right outcome
  - At a minimum of adverse effects

- **Means:**
  - Genotyping of genetic polymorphisms (SNPs)
  - Gene expression analysis
  - Gene methylation analysis

Personalised medecine: tailored treatments

- Biomarkers are involved in the disease pathology

  Example: trastuzumab - Her-2/neu+ breast cancer

- Biomarkers are "anonymous" indicators of a therapeutic effect

Personalised medicine: patenting

- Known drug
- Known treatment
- New selection of a subgroup of patients
- Based on genotyping a SNP

➢ claim(s) to the diagnostic method

➢ claim(s) to a second/further medical use of the drug (Art. 54(5) EPC)

Personalised medicine: claims

- **Type I (without selection step)**

  Drug X for use in a method of treatment of disease Y in a patient ***having*** allele A / genotype AA of SNP Z / high/low expression of marker B.

- **Type II (with passive selection step)**

  Drug X for use in a method of treatment of disease Y in a patient ***having been selected to have*** allele A / genotype AA of SNP Z / high/low expression of marker B.

- **Type III (with active selection step)**

  Drug X for use in a method of treatment of disease Y in a patient having allele A / genotype AA of SNP Z and wherein the method ***comprises the step of determining*** whether the patient has allele A / genotype AA of SNP Z / high/low expression of marker B.

Personalised medicine: claims

Novelty and inventive step of Type I to III claims

- Novelty

  - of these claims can be acknowledged provided that the prior art does not disclose the treatment of at least one patient ***having*** allele A / genotype AA of SNP Z / high/low expression of marker B (beyond resonable doubt)

- Inventive step

  - Purposeful selection of patients: marker is shown to be associated with a technical effect such as increased response, reduced secondary effects, etc.

Article 53(c) – Diagnostic methods

Terminology and definitions (G 1/04)

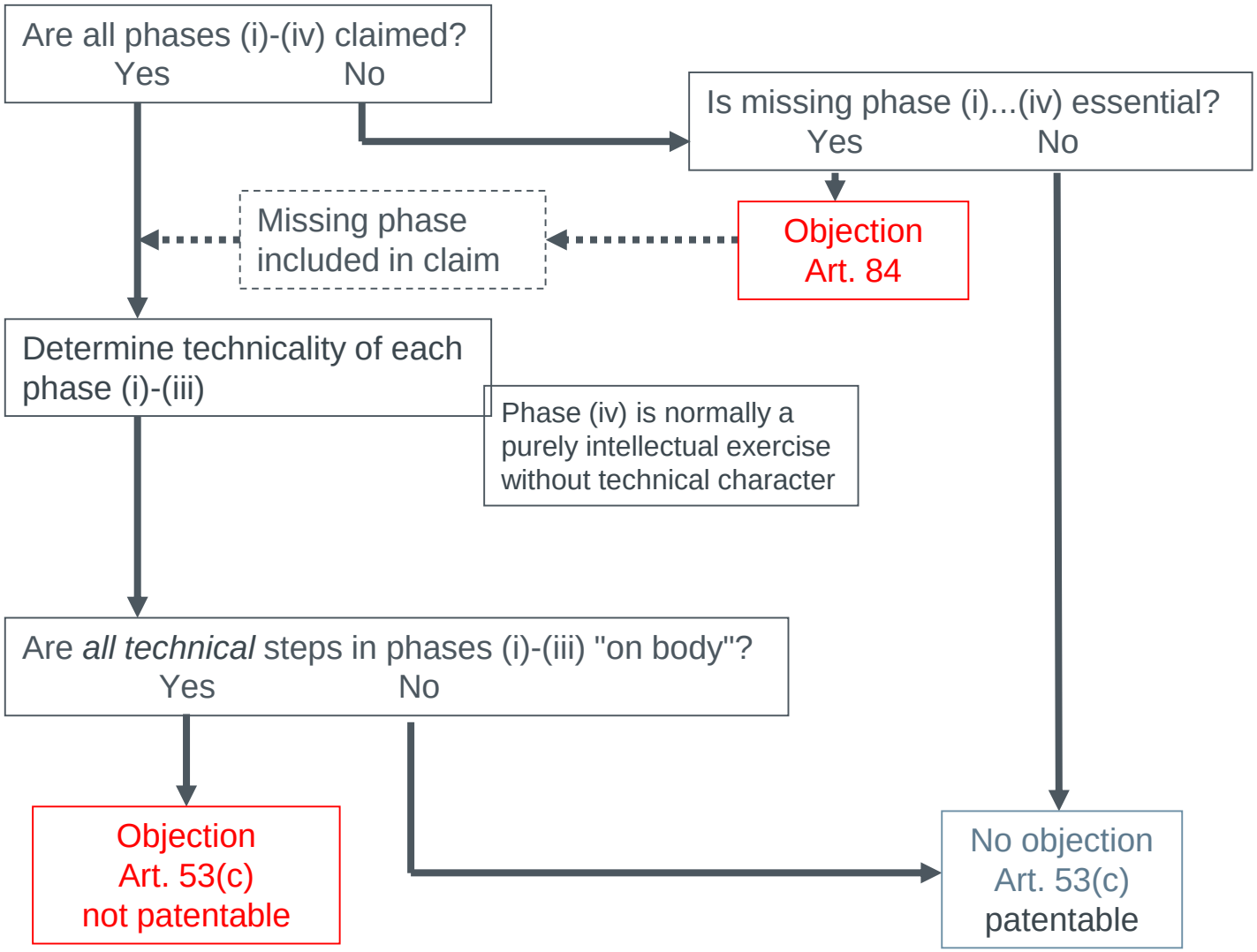
(i) Examination phase involving the collection of data
(ii) Comparison with standard values
(iii) Finding of any significant deviation, i.e. a symptom

Steps (i)-(iii) are preceding steps constitutive for making a diagnosis (intermediate findings of diagnostic relevance)

(iv) Attribution of deviation to a particular clinical picture, the diagnosis for curative purposes *stricto sensu* ("deductive medical or veterinary decision phase")

All of steps (i) to (iv) must be present at least implicitly for a claim to fall under the prohibition of Article 53(c) EPC.

Article 53(c) – diagnosis



Diagnostic methods – T 125/02

	Phase	Technical	On body
Claim 1 Method for ascertaining the current lung function of a human subject ...			
▪ measuring endogenous NO content ... in a sample of exhaled air	(i)	Yes	Yes
Claim 2 Method according to claim 1, further comprising			
▪ comparing said measured content ... to endogenous NO content ... of a human subject having complete or unimpaired respiratory tract function	(ii)	No	
▪ interpreting a deviation manifested by said comparison as an indication of impaired respiratory tract function.	(iii) (iv)	No No	

Article 53(c) Surgery

"... treatment of the **human or animal body** by surgery"

Patents are not to be granted for:

- incisions, endoscopy, ablation
- dialysis, autologous transfusion

Patents could be granted for:

- in vitro methods (e.g. blood testing)
- treatment of a dead body (e.g. excision of heart valves from cadavers)
- treatment of laboratory animals if they are subsequently sacrificed (T1262/04)

Article 53(c) – Surgery

- A **single** surgical or therapeutic step in a **multi-step** method is sufficient to exclude the whole claim from patentability (G 1/07).

- **A surgical step may also be implicit from the description or dependent claims.**

- **However, methods for merely obtaining information from the living body** such as X-ray investigations are **not** considered as surgical or therapeutic steps and are therefore **not** excluded from patentability under Art. 53(c).

- **Operating a device** is **not** excluded from patentability under Art. 53(c), as long as there is no functional link between the operating step and the effect on the body (the therapy)

Article 53(c) – Surgery

Indicators of medical character

- Involvement of a person of medical competence
  (medical/veterinary practitioner or other medically trained person, or supervision by such a person) (G 1/07)

- Harmful side effects and health risks for the patient
  (e.g. laser irradiation of an artificial lenticule secured to the cornea, see T 24/91)

Article 53(c) – surgery (G 1/07)

Surgical treatment (G 1/07)

- The exclusion should not be applied to uncritical methods involving only a minor intervention and no substantial health risk, when carried out with the required care and skill.

- The **nature** of the treatment is decisive, rather than its purpose (which may be non-curative, e.g. sterilisation or insemination, or even non-medical, e.g. cosmetic or agricultural). Surgical treatments are not limited to those pursuing therapeutic purposes.

Article 53(c) – surgery (G 1/07)

- Includes physical interventions on the body which require professional medical skills to be carried out and which involve health risks even when carried out with the required medical professional care and expertise.
  - Examples of such interventions include **invasive** procedures using instruments (e.g. non-routine injections such as the injection of a contrast agent into the heart, endoscopy, and the excision/opening of body parts), and the **non-invasive** repositioning of body limbs.

- Does not include methods in respect of which the interests of public health or the protection of patients and the freedom of the medical profession to apply the treatment of choice to their patients do not call for their exclusion from patentability, e.g.. tattooing, piercing, hair removal by laser radiation or micro-abrasion of skin

Article 53(c): Surgery, therapy and diagnosis

An objection under Art. 53(c) EPC can be avoided by limiting the claim to a non-therapeutic, non-surgical or non-diagnostic method, even though these terms are not originally disclosed

("undisclosed disclaimer", G 1/03, G 2/03)

- However, at least one non-medical application must have been disclosed.

- A claim may not become contradictive in itself by terming an actually medical method as non-therapeutic, non-surgical or non-diagnostic (T 67/02).

Thank you very much for your attention!