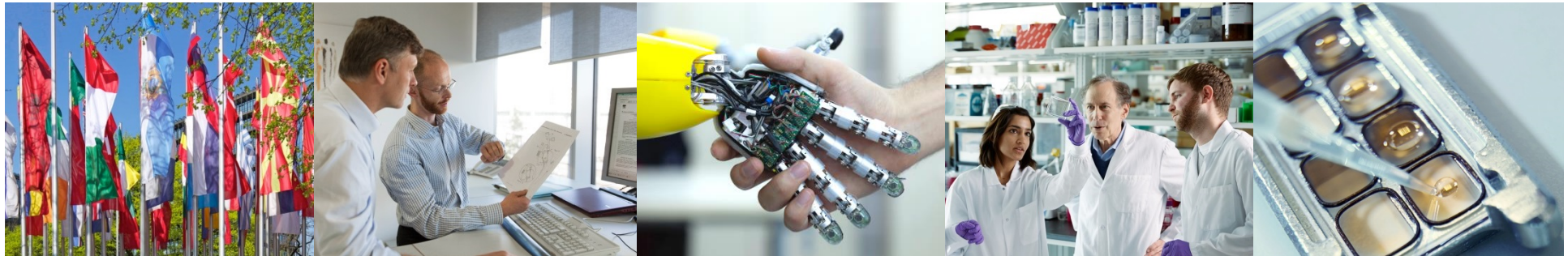




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Examination Matters – webinar series in the medical field

Therapeutic methods – Article 53(c) EPC



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Presenting today



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Therapeutic methods – Article 53(c) EPC



Agenda

- § Therapy, surgery, cosmetic treatment – 5W
- § Examples
 - Performance boosting
 - Only cosmetic?
 - Internal life of devices
- § Getting it done
 - Claim redrafting
 - Application of Article 54(4), (5) EPC
 - Undisclosed disclaimer
 - Beware: Article 53(c), 54(5) and 84 EPC trap
- § Q&A

Therapy, surgery, cosmetic treatment – 5W



Article 53(c) EPC – an overview

- § European patents shall not be granted in respect of methods for **treatment of the human or animal body by surgery or therapy**
- § This provision **shall not apply to products, in particular substances or compositions**, for use in these methods

Therapy, surgery, cosmetic treatment – 5W



Therapy – EPC point of view

- § Therapy contributes to **full or partial healing, relief or restoration of fitness**
- § Therapy includes treating problems caused by natural processes: age, birth ...
- § Prophylaxis and vaccination is therapy

Therapy, surgery, cosmetic treatment – 5W



Surgery – EPC point of view

Surgery:

- § requires professional **medical expertise**
- § and entails a **substantial health risk**
- § **Not surgical**: tattooing, piercing, hair removal by optical radiation and micro-abrasion ...

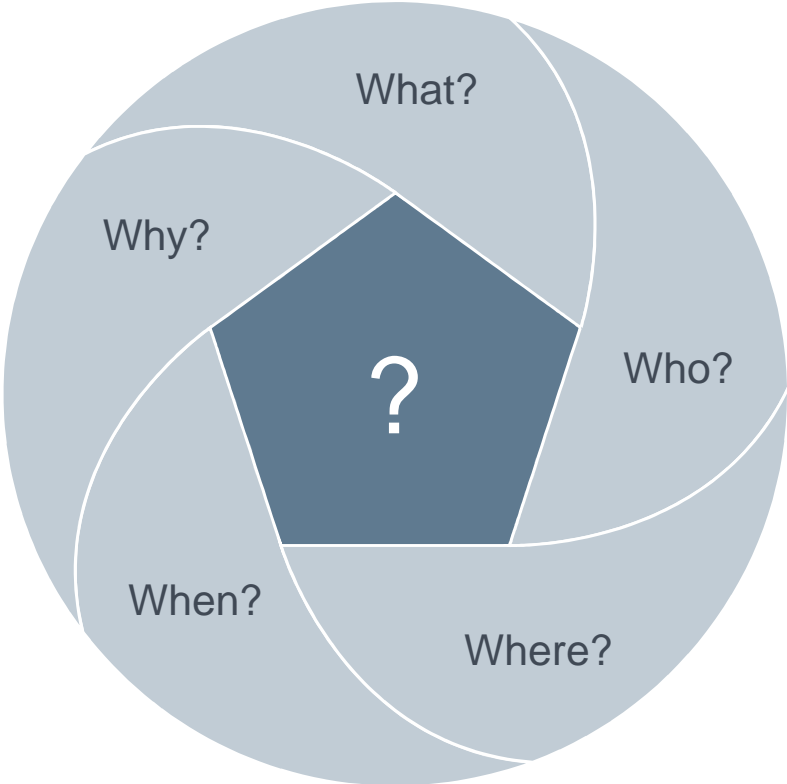
Therapy, surgery, cosmetic treatment – 5W



Cosmetic or aesthetic treatment

- § Purpose matters – beware of **aesthetic surgery!**
- § Defining the **exact purpose** of treatment and a group of patients / users makes a difference!

Therapy, surgery, cosmetic treatment – 5W



Therapy, surgery, cosmetic treatment – 5W



What?

- § A **single** therapeutic / surgical (TS) step renders the whole claimed method TS
- § **Broad** definition of "pathological conditions"



Therapy, surgery, cosmetic treatment – 5W

Who?

It does **not** matter:

- § whether the method is **computer-implemented**, robot-performed or human-performed ...
- § what **practitioner** is supposed to perform it: a surgeon, a vet, a paramedic, a dentist, a midwife, a first aid trained soldier, a fire brigade member ...
- § whether the patient / user is a **human** or an **animal**



Therapy, surgery, cosmetic treatment – 5W



Where?

- § It is **not** required that the method is performed in a **hospital, clinic ...**
- § ... but if it is provided in **commercial** space (spas, shopping centres, at the hairdresser's ...), it suggests a non-therapeutic interpretation
- § Presence of the **body** is required: extra-corporeal or virtual methods are not TS



Therapy, surgery, cosmetic treatment – 5W



When?

- § Is there a **spatial / temporal** split between the method and TS steps (pre-planning, manufacture of an implant)?
- § Imaging, calculation methods or method referring to "internal life" of a device are not TS even when performed during a TS procedure



Therapy, surgery, cosmetic treatment – 5W

Why?

§ In **therapy / cosmetic application**, the **purpose** matters:

Is a pathological or aesthetic problem treated?
Are patients healthy or ill?

§ In **surgery** the **action / nature of treatment** matters:

What is done?

Aesthetic surgery is thus still surgery!



Therapeutic methods – Article 53(c) EPC



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Ü Therapy, surgery, cosmetic treatment – 5W

§ Examples

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§ Getting it done

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§ Q&A

Examples



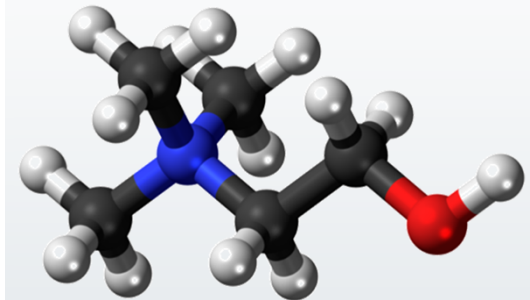
Performance boosting (1)

The use of choline

for **reducing the perception of fatigue**

in a **person about to participate in major exercise or having completed major exercise.**

T 0469/94



Examples



Performance boosting (2)

Not therapy!

- § The claim refers only to an **increase of athletic performance of a healthy subject**
- § Fatigue due to sport activity is a **non-pathological** state

Therapeutic methods – Article 53(c) EPC



Agenda

Ü Therapy, surgery, cosmetic treatment – 5W

§ **Examples**

- Performance boosting
- **Only cosmetic?**
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Examples



Only cosmetic? (1)

A method of **cleaning plaque and stains from teeth** by:

§ applying an **aqueous composition** of lanthanum ...

T 290/86

Examples



Only cosmetic? (2)

Therapy!

The cosmetic effect (white teeth) cannot be separated from the therapeutic effect (periodontosis prevention)

But

Article 54(5) EPC form allowable

Therapeutic methods – Article 53(c) EPC



Agenda

Ü Therapy, surgery, cosmetic treatment – 5W

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- **Internal life of devices**

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Examples

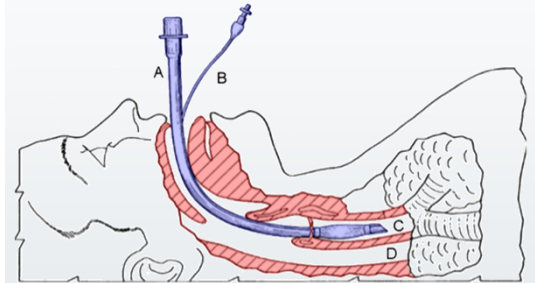


Internal life of devices (1)

Method for **determining airway pressure** of a lung ventilated by an artificial ventilator comprising steps of:

- § Measuring CO₂ concentration of the expired gas
- § **changing the airway pressure of the artificial ventilator** accordingly

T 1680/08



Examples



Internal life of devices (2)

Therapy!

Because life – saving!

But

apparatus claim granted

Therapeutic methods – Article 53(c) EPC



Agenda

Ü Therapy, surgery, cosmetic treatment – 5W

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§ **Getting it done**

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§ Q&A

Getting it done



Get rid of the body

§ *in vitro*, in cell culture, for treatment of materials, virtual ...

§ methods applicable in non-medical field:

- endoscopy for pipe inspection
- particle irradiation for material engineering
- ...

Getting it done



Specify your target

§ Split your user pool into groups:

- cosmetic, non-therapeutic, fun, performance boosting:
(**method claim**)
- therapeutic (**medical use claim**)

§ The groups must be clearly distinguishable

§ Take care: Article 123(2) EPC applies!

Therapeutic methods – Article 53(c) EPC



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§ Q&A

Getting it done



Use Article 54(4), (5) EPC

But it refers to **substances and compositions only**.

- § Substance: a compound or an element;
- § Composition: chemical combination of substances;
- § Devices are generally **not** substances.
- § Substances have a **biochemical** effect on the body; effect of devices are primarily **physical**.

Getting it done



Example – the claim

**Original
claim 1**

a method of skin treatment, wherein substance X is administered topically ...

§ **No**: exclusion under Article 53(c)

§ description mentions:

- **cosmetic applications** (rejuvenation)
- **therapeutic applications** (treatment of acne, lesions ...)

Getting it done



Example – split and use two claim forms

Claim 1a

A cosmetic, non-therapeutic method of skin rejuvenation, wherein substance X is administered topically ...

Claim 1b

Substance X for use in the method of skin lesion treatment ...

Getting it done



Example – summary

Split the claim into

a cosmetic method claim

a first / second medical use claim

Caveat

possible issues with Article 84 EPC –
can the therapeutic and cosmetic application
be separated?

Therapeutic methods – Article 53(c) EPC



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Getting it done



Undisclosed disclaimer (1)

- § Possibility to disclaim subject-matter excluded from patentability under Article 53(c) EPC
- § It **does not** violate Article 123(2) EPC just by being introduced into a claim;

But

- § A disclaimer **relevant** for the **assessment of inventive step or sufficiency of disclosure** violates Article 123(2) EPC
- § A claim still must meet the requirements of **clarity and conciseness**

G 1/03

G 2/10

G 1/16

Getting it done



Undisclosed disclaimer (2)

- § Possibility to disclaim subject-matter excluded from patentability under Article 53(c) EPC
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But

- § A disclaimer **relevant** for the **assessment of inventive step or sufficiency of disclosure** violates Article 123(2) EPC
- § A claim still must meet the requirements of **clarity and conciseness**

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Therapeutic methods – Article 53(c) EPC



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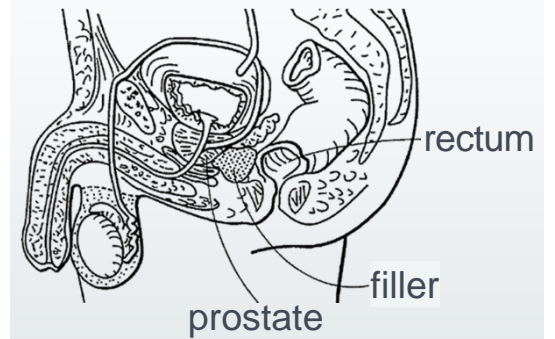
Getting it done



Beware ...

A **filler** injectable a prostate and a rectum prior to radiation treatment whereby when the prostate is subsequently treated by radiation the filler reduces passage of radiation into the rectum

T 1758/15



Getting it done



Beware – Article 54(5) EPC

The **filler** for injection and for use in a method of radiation treatment ...

No – the filler has a mechanical role; its chemical composition is secondary

The claim form under Article 54(5) EPC is not correct.

Getting it done



Beware – Article 53(c) EPC

A method of injecting the filler between a prostate and a rectum prior to radiation treatment ...

No – it is a TS method

Exclusion under Article 53(c) EPC

Getting it done



Beware – Article 84 EPC

A method of injecting said filler material ... **excluding methods according to Article 53(c) EPC**

No – When you remove therapeutic embodiments, what is left?
An "empty" claim.

Article 84 EPC violation

Therapeutic methods – Article 53(c) EPC



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§ Q&A

Questions



Questions

now

via chat

later

via mail è academy@epo.org