Examination Matters – webinar series in the medical field

Therapeutic methods – Article 53(c) EPC

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Presenting today

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Since 2008 at the EPO, field of medical equipment
(mainly A61N)
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

What?

Why?

Who?

When?

Where?

?
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?

β It is not required that the method is performed in a hospital, clinic...

β ... but if it is provided in commercial space (spas, shopping centres, at the hairdresser’s...), it suggests a non-therapeutic interpretation

β 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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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.
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

- Therapy, surgery, cosmetic treatment – 5W

**Examples**
- Performance boosting
- *Only cosmetic?*
- Internal life of devices

**Getting it done**
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**Q&A**
Examples

Only cosmetic? (1)

A method of cleaning plaque and stains from teeth by:

- applying an aqueous composition of lanthanum ...
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

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Q&A
Examples

Internal life of devices (1)

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

β Measuring CO₂ concentration of the expired gas

β changing the airway pressure of the artificial ventilator accordingly
Examples

Internal life of devices (2)

Therapy!
Because life – saving!

But
apparatus claim granted
Therapeutic methods – Article 53(c) EPC

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Q&A
Getting it done

Get rid of the body

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

β methods applicable in non-medical field:
  • endoscopy for pipe inspection
  • particle irradiation for material engineering
  • ...

European Patent Office
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**.
Example – the claim

Original claim 1:

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

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

ℹ️ description mentions:

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

European Patent Office
Getting it done

Example – split and use two claim forms

<table>
<thead>
<tr>
<th>Claim 1a</th>
<th>A cosmetic, non-therapeutic method of skin rejuvenation, wherein substance X is administered topically ...</th>
</tr>
</thead>
<tbody>
<tr>
<td>Claim 1b</td>
<td>Substance X for use in the method of skin lesion treatment ...</td>
</tr>
</tbody>
</table>
## Example – summary

<table>
<thead>
<tr>
<th><strong>Split the claim into</strong></th>
<th>a cosmetic method claim</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>a first / second medical use claim</td>
</tr>
<tr>
<td><strong>Caveat</strong></td>
<td>possible issues with Article 84 EPC – can the therapeutic and cosmetic application be separated?</td>
</tr>
</tbody>
</table>
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Q&A
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
Getting it done

Undisclosed disclaimer (2)

 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
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Q&A
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.
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

now via chat

later via mail academy@epo.org