How to get patents in healthcare
Patenting surgical, therapeutic and diagnostic methods

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EPO Webinar
Introduction

Objective

Show how we deal with the exceptions from patentability concerning medical methods

- Patentability requirements
- EPO's practice in view of the Guidelines as updated in 2017
- Practical considerations for drafting successful applications
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Medical electronics and medical mechanics
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Patenting surgical, therapeutic and diagnostic methods

Agenda

- Legal basis and general aspects
- Treatment by surgery and therapy
- Diagnostic methods
- Conclusion
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.
General aspects

Surgery, therapy, diagnosis

- Three separate alternative or cumulative exclusions
- Only methods practised on the living body
- Applies to humans and animals
General aspects

Surgery/therapy vs. diagnosis

Surgery and therapy

A single surgical or therapeutic step suffices to render the claimed method surgical or therapeutic

Diagnosis

The whole diagnostic sequence must be present for the method to be diagnostic: four steps of a diagnostic method
Patenting surgical, therapeutic and diagnostic methods

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General aspects

Surgery vs. therapy

**Surgery**

The kind of action / nature of the treatment is decisive rather than its purpose

β “Maintaining the life and health of the subject is important”

**Therapy**

The purpose and effect of the treatment are decisive:

β Maintaining or restoring health
Treatment by surgery

Basic principle

Excluded

Substantial physical interventions representing the core of the medical profession's activities

β require professional medical skills (but cannot depend on the person carrying it out)

β involve substantial health risks

Allowable

β Uncritical methods involving only a minor intervention

β No substantial health risk
Example 1

Method for aligning a surgical drill with a point, comprising the steps of:

§ detecting the position of the drill with a tracking system;

§ aligning the drill with the point using a navigation system.

Coefficients aligning the drill = moving the drill inside the body

Coefficients surgical step

Is the method excluded under Article 53(c) EPC?

Yes: method excluded

European Patent Office
Example 1

Possible way out

A method for determining alignment of a surgical drill with a point, comprising the steps of:

1. Detecting the position of the drill with a tracking system;
2. Determining alignment of the distal end of the drill with the point.

Functional / temporal separation: insertion of the drill not part of the claimed steps.
Treatment by surgery and therapy

How to avoid an objection

- claimed step
- claimed step
- temporal separation
- claimed step

spatial / functional separation

T 1599/09, T 2438/11
T 923/08

T 245/87, T 836/08
T 992/03, T 266/07
T 238/06
Treatment by surgery

Further examples

Excluded

- Endoscopy, catheterisation, minimally invasive surgery
- Castration, artificial insemination
- Venipuncture and withdrawal of blood from a donor
- Injecting a contrast agent into the heart

Not excluded

- Injecting a contrast agent into a vein remote from the artery
- Tattooing, piercing, hair removal by optical radiation
- Micro abrasion of the skin
Treatment by therapy

Basic principle and examples

Excluded

- Curative therapy
- Symptomatic therapy: e.g. relief of pain of natural origin
- Prophylactic therapy: e.g. vaccination, immunostimulation

Allowable

- Method has no therapeutic purpose and effect
- Contraception (if no therapeutic effect)
- Use of spectacle lenses to correct ametropia
Example 2

A method for determining airway pressure of a lung ventilated by an artificial ventilator, comprising the steps of:

- obtaining CO2 concentration of the expired gas;
- changing the airway pressure of the artificial ventilator.

}  step of artificial ventilation implicit from the claim
}  aims at keeping the patient alive
}  therapeutic step
}  not relevant that it is a "method for determining ..."

Is the method excluded under Article 53(c) EPC?

Yes: method excluded
Example 2

**Possible way out: automation of the method?**

A computer-implemented method for determining airway pressure of a lung ventilated by an artificial ventilator, comprising the steps of:

- automatically obtaining CO2 concentration of the expired gas;
- automatically changing the airway pressure of the artificial ventilator.

partial or full automation or computer-implementation of a surgical or therapeutic method does not allow to escape the exception of Article 53(c) EPC

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Based on T 1680/08
GL G-II, 4.2.1.1, 2

Does full automation allow to escape the exclusion?

No: automation does not allow to escape exclusion

therapeutic method
Example 3

The use of a compound of the group of choline for increasing the acetylcholine level in the brain and thereby reducing the perception of fatigue in a person about to participate in major exercise.

It is known that choline exhibits a therapeutically relevant activity if administered over a prolonged period.

} "use" claim = "method" claim

} the therapeutic effect and the effect of reducing fatigue are readily distinguishable because they involve groups of persons (or patients) undoubtedly distinct

Is the method excluded under Article 53(c) EPC?
No: the method is not excluded

based on T 469/94

not a therapeutic method
Treatment by therapy

How to avoid an objection

Limiting the claim to the non-therapeutic effect (e.g. cosmetic)

Possible when

- The group of persons treated can be clearly identified as healthy vs. suffering from a pathological condition
- Parameters of the method (e.g. times) are so different that no unwanted overlap with treatment

Examples when not possible to separate the effects

- Removal of plaque
- Use of a perfume composition for releasing persons from sleepiness
Treatment by surgery and therapy

How to avoid an objection – second medical use

Method of treating disease A with substance B

Substance B for use in treatment of disease A

Claim **new if**
substance B known but not in treatment of disease A

⚠ Applies only for **substances or compositions**
β Not for a device (possible lack of novelty)

Article 54(4), (5) EPC
G 5/83, G 2/08
GL F-IV, 4.13; G-VI, 7.1.1

Substance/composition?

T 2003/08
T 0773/10, T 1099/09
Treatment by surgery and therapy

How to avoid an objection

- Device, computer program, storage media
- Living human or animal body not present
  - In vitro (fluids or tissues already removed)
  - Method practiced on a model or a cadaver
  - Simulation method
- The medical step / the medical application is disclaimed

Possible problems of Article 84 or 123(2) EPC
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Diagnostic methods

The four phases

For the method claim to fall under the exception of Art. 53(c) it must include steps relating to all of the following phases:

(i) examination phase involving the collection of data
(ii) comparison with standard values
(iii) finding of any significant deviation, i.e. a symptom
(iv) attribution of deviation to a particular clinical picture ("deductive medical or veterinary decision phase")

> All phases (i) – (iv) are required to be present at least implicitly in the claim

> All method steps of a technical nature belonging to phases (i)-(iii) must be "practised on the human or animal body"
Example 4

A method of diagnosing an amyloidogenic disorder comprising:
- illuminating an ocular lens;
- detecting light signals emitted from the lens;
- analysing said detected light signals by Raman spectroscopy to detect protein aggregates;
- wherein the presence of aggregates as compared with a normal control value indicates that the patient is at risk of developing an amyloidogenic disorder.
Example 4

Phase (i)

A method of diagnosing an amyloidogenic disorder comprising:

- illuminating an ocular lens;
- detecting light signals emitted from the lens;

(i) examination, collection of data

} phase (i) involves steps of a technical nature

practised on the body

} Presence of human or animal body, irrespective of type or intensity of interaction

Is phase (i) present?

(i) examination phase involving the collection of data

Yes: phase (i) present

Practiced on the body
Example 4

Phases (ii), (iii)

phases (ii), (iii)

} phases (ii)-(iii) "predominantly of non-technical nature" (within the meaning of G 1/04), not concerned with the criterion "practised on the human or animal body"

wherein the presence of aggregates as compared with a normal control value indicates that the patient is at risk of developing an amyloidogenic disorder.
Example 4

Phase (iv)

A method of diagnosing an amyloidogenic disorder comprising:
- illuminating an ocular lens;
- detecting light signals emitted from the lens;
- analysing said detected light signals by Raman spectroscopy to detect protein aggregates;
- wherein the presence of aggregates as compared with a normal control value indicates that the patient is at risk of developing an amyloidogenic disorder.

} phase (iv) not concerned with the criterion "practised on the human or animal body"

Is phase (iv) present?
(iv) attribution of deviation to a particular clinical picture ("deductive medical or veterinary decision phase")

Yes: phase (iv) present

This is a particular clinical picture
Example 4

Conclusion

A method of diagnosing an amyloidogenic disorder comprising:

1. illuminating an ocular lens;
2. detecting light signals emitted from the lens;
3. analysing said detected light signals by Raman spectroscopy to detect protein aggregates;
4. wherein the presence of aggregates as compared with a normal control value indicates that the patient is at risk of developing an amyloidogenic disorder.

Diagnostic method

phases (i) – (iv) present
phase (i) technical and practised on the body
phases (ii)-(iii) “predominantly of non-technical nature”, not concerned with the criterion "practised on the body"
phase (iv) not concerned with the criterion "practised on the body"
Example 4

Possible way out: automation of the method?

A computer-implemented method of diagnosing an amyloidogenic disorder comprising:

- illuminating an ocular lens;
- detecting light signals emitted from the lens;
- automatically analysing said detected light signals by Raman spectroscopy to detect protein aggregates;
- wherein a processor determines that the presence of aggregates as compared with a normal control value indicates that the patient is at risk of developing an amyloidogenic disorder.

Practical consequence of GL G-II, 4.2.1.3: partial or full automation or computer-implementation of a diagnostic method does not allow to escape the exception of Article 53(c) EPC.

Does full automation or computer-implementation allow to escape exclusion?

No: automation does not allow to escape exclusion.

Diagnostic method
Diagnostic methods

How to avoid an objection

β phase (i) not practised on the body
  • data acquired from in-vitro samples

β phase (i) not present
  • data acquired from a database
  • claim directed to data processing only

β no phase (iv) (deductive medical or veterinary decision)
  • method directed only to data acquisition from the patient
  • method provides only intermediate findings

! possible problem of Article 84 or 123(2) EPC when deleting steps from the claimed method
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Conclusion
Conclusion

There are many ways of protecting your invention in the field of healthcare.

- Consider possible scenarios already when drafting the application.
- Be aware of the other requirements of patentability.
- ... in particular when your invention involves computer-implemented inventions.

See the other webinars of the series "How to get patents in healthcare".
Medical methods

Questions

now via chat

later via mail academy@epo.org
Additional example – Q&A session

A blood processing method comprising the steps of:
- providing a blood processing circuit;
- conveying blood from a donor;
- processing blood for separation of a blood component;
- returning blood to the donor.

- implicit step of venipuncture of the median cubital vein
- substantial health risks
- surgical step

- withdrawal of blood = partial removal of an organ
- surgical step

based on T 1075/06