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How to get patents in healthcare

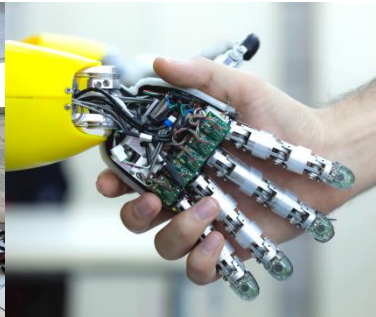
Patenting surgical, therapeutic and diagnostic methods



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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

Presenting today



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At the EPO since 2003

Medical electronics and medical mechanics

Expert in **Patentability of Medical Methods**

Expert in Computer-Implemented Inventions

Mechanical engineer

PhD Medical image processing

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Patenting surgical, therapeutic and diagnostic methods



Agenda

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

Legal basis



Exceptions to patentability

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.

Article 53 EPC

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**

Article 53(c) EPC
G 1/04, G 1/07

Patenting surgical, therapeutic and diagnostic methods



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- Ü Legal basis and general aspects
- § **Treatment by surgery and therapy**
- § Diagnostic methods
- § Conclusion

General aspects



Surgery vs. therapy

Surgery

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

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

Therapy

The **purpose and effect of the treatment** are decisive:

§ **Maintaining or restoring** health

Article 53(c) EPC
G 1/04, G 1/07

Treatment by surgery



Basic principle

⊘ Excluded

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

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

§ involve **substantial health risks**

ü Allowable

§ Uncritical methods involving only a minor intervention

§ No substantial health risk

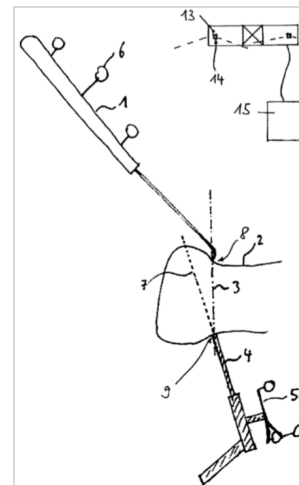
G 1/07

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.



based on T 2438/11

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

Yes: method excluded

 **surgical method**

} **aligning the drill = moving the drill inside the body**

} **surgical step**

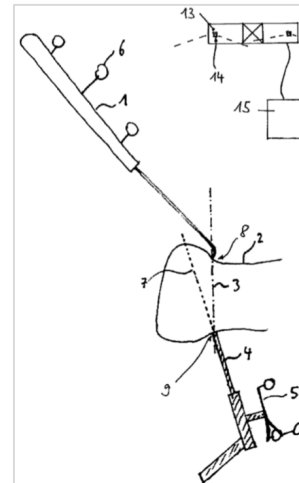
Example 1



Possible way out

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

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

adapted from T 836/08

Does omission of the surgical step allow to escape exclusion?

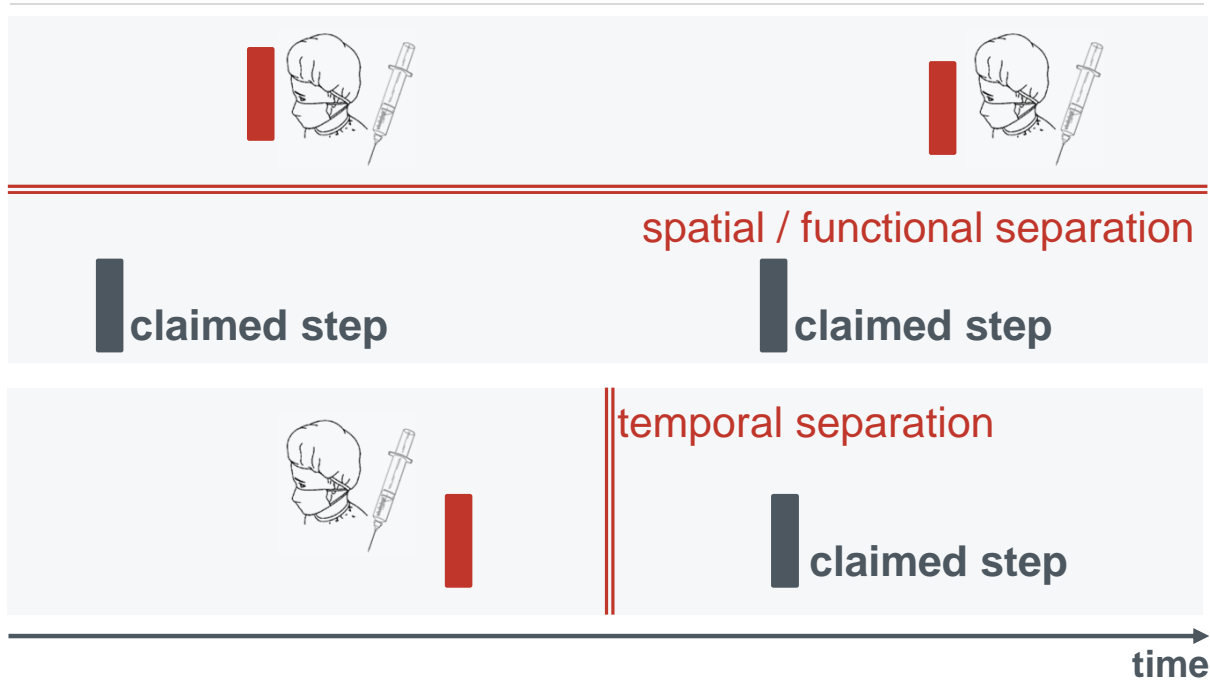
Yes: the surgical step is no longer part of the claim

Ü method not excluded

Treatment by surgery and therapy



How to avoid an objection



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

G 1/07, T 1075/06



T 992/03, T 1075/06



T 663/02

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

G 1/07
T 19/86

 T 81/84, T 443/01
T 19/86, T 780/89
T 290/86, T 820/92
T 1635/09

 T 2420/13

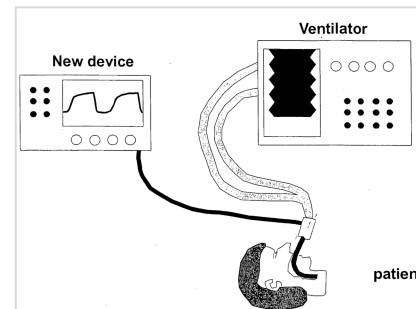
Example 2



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 ..."**



based on T 1680/08

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

Yes: method excluded

 **therapeutic method**

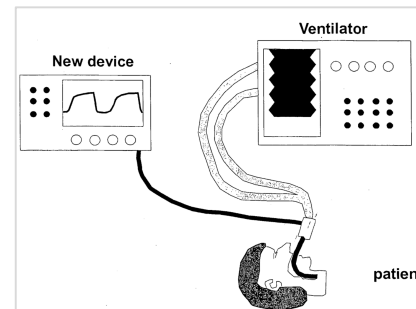
Example 2



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**

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**

based on T 469/94

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

No: the method is not excluded

Ü not a therapeutic method

Treatment by therapy



How to avoid an objection

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

ü 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

T 469/94



T 290/86, T 158/13

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**

§ 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?

Ü 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

Article 53(c) EPC

GL G-II, 4.2; 4.2.1; 4.2.2

G 1/16, G 2/10, G 1/03

T 1487/09

Patenting surgical, therapeutic and diagnostic methods



Agenda

- Ü Legal basis and general aspects
- Ü Treatment by surgery and therapy
- § **Diagnostic methods**
- § Conclusion

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"**

GL G-II, 4.2.1.3

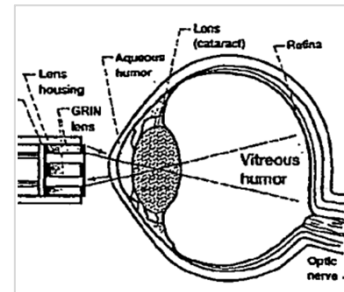
(based on G 1/04 r. 5)

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.



based on T 1016/10

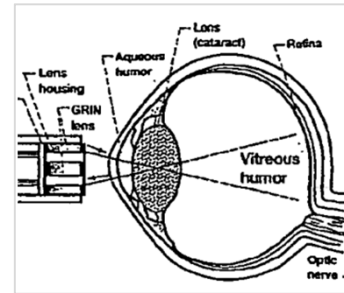
Example 4



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

based on T 1016/10

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.

based on T 1016/10

GL G-II, 4.2.1.3

Are phases (ii), (iii) present?

(ii) comparison with standard values

(iii) finding of any significant deviation, i.e. a symptom

Yes: phases (ii), (iii) present

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"

based on T 1016/10

GL G-II, 4.2.1.3

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

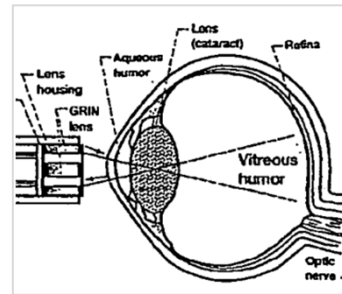
Example 4



Conclusion

A method of diagnosing an amyloidogenic disorder comprising:

- § 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.



 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:

[...]

- } 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**

based on T 1016/10

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

§ phase (i) not practised on the body

- data acquired from in-vitro samples

§ phase (i) not present

- data acquired from a database
- claim directed to data processing only

§ 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

G 1/04, G 1/07

Patenting surgical, therapeutic and diagnostic methods



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- ü Treatment by surgery and therapy
- ü Diagnostic methods
- § **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 è academy@epo.org

Additional example – Q&A session



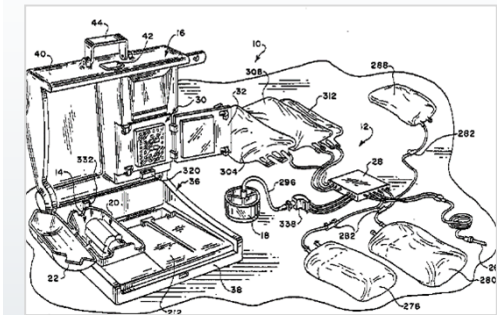
A blood processing method comprising the steps of:

- § 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



surgical method