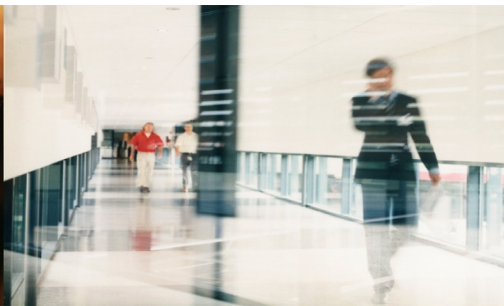


Medical Methods under the European Patent Convention

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26-30 November 2012



Overview

General Considerations

Diagnostic Methods

Therapy and Surgery: Common Aspects

Therapeutic Methods

First and Further Medical Use Protection

General Aspects

Article 53 EPC 2000 (Exceptions from 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.

- purely editorial change of Art. 52(4) EPC 1973
- does not change the actual legal position
- present interpretation of Art. 52(4) EPC 1973 remains valid (G1/04)

General Aspects

Purpose underlying Article 53(c) EPC:

Medical and veterinary activities should not be restrained by patent rights, i.e. med./vet. practitioners should not be hindered from exercising their professional skills when helping their patients (G5/83, G1/04)

i.e. socio-ethical and public health considerations:

- nobody who wants to use these methods as part of the medical treatment should be prevented from doing this by patents (T24/91)
- med./vet. practitioners should not be hindered in the exercise of their professional skills, i.e. prevented from giving the best medical treatment to their patients (T245/87)

Involvement of the Med./Vet. Practitioner

- even though not a decisive criterion, the involvement of the med./vet. practitioner is a **useful indication** that a claimed method may be excluded
- not the sole criterion: the purpose and the inevitable effect of the step at issue are much more important (T329/94)
- the fact that a method can be performed by a person without specialist medical knowledge such as a technician does not necessarily imply that it is allowable under Art. 53(c) (T116/85, T182/90, T964/99)

Health Risks

A method for treatment of the human body can normally be said to fall within the exclusion of the first sentence of Article 52(4) EPC 1973 at least in those cases where, in view of the **health risks** connected with such a treatment, it has to be performed by a physician or under his supervision (e.g. laser ablation of an artificial lenticule secured to the cornea; T24/91)

harmful side effects and health risks:

→ med./vet. practitioner is normally involved

→ indication that the method may fall under the exclusion clause

"the human or animal body"

Art. 53(c): "... methods for treatment **of** the human or animal body by **surgery or therapy** and **diagnostic** methods practised **on** the human or animal body"

G1/04 (diagnosis):

criterion "practised on the human or animal body" is satisfied if the performance of the respective step implies **any interaction** with the human or animal body, necessitating the presence of the latter (a direct physical interaction is not required)

Guidelines C-IV, 4.8.1:

only methods performed on the **living** body are excluded
treatment of the dead body is not objectionable (e.g. excision of heart valves from cadavers for preservation purposes)

"the human or animal body"

Exclusion does **not** apply to "**in vitro**" methods (cf. T310/99):

- e.g. testing or processing of bodily liquids (urine, blood, etc.) or tissues for determining the presence or concentration of constituents such as glucose
- unless the sampling/extraction itself (which is normally surgical in case of blood) forms part of the claimed procedure (T329/94)

Claim Category

Art. 53(c) 2nd sentence:

"this provision shall not apply to products, in particular substances or compositions, for use in any of these methods"

claim categories (Guidelines C-III, 3.1):

- physical entities (product, apparatus)
- activities (process, use)

"apparatus or product [comprising structural features] for use in a medical method [comprising method steps]"

→ **not excluded** under Art. 53(c)

"use of an apparatus or product [comprising structural features] in a medical method [comprising method steps]"

→ **excluded** under Art. 53(c)

Implicit Step

Independent claim:

measuring blood pressure

Dependent claim or description:

measurement is performed invasively by catheterisation (surgical)

- the independent claim is also objectionable as surgical since it encompasses the invasive measurement
- if non-invasive measurement by means of a cuff is disclosed, the objection can be overcome by
 1. limiting the independent claim to non-invasively measuring blood pressure by means of a cuff
 2. deleting the dependent claim or the respective passages from the description

Implicit Step (T1005/98)

A method for manufacturing a knee endoprosthesis ... wherein the prosthesis requires a surgical operation ...

- (a) obtaining a pre-operative image of the injured knee joint
- (b) correction of the pre-operative image ...
- (c) obtaining a post-operative image ...
- (d) juxtaposition of the pre-operative image and the post-operative image ... for determining the differences between the two images
- (e) manufacturing of at least a femoral and a tibial component of an endoprosthesis ... based on the differences

- description gives no room for any other interpretation than the **absolute necessity of a surgical operation** to be carried out on the patient before taking the post-operative image
- even though not claimed as such, the method **implies** a surgical step between steps (a) and (c)

Disclaimer

An objection under Art. 53(c) EPC can be avoided by removing the subject-matter falling under the exclusion by means of a disclaimer, even though the respective terms are not originally disclosed ("undisclosed disclaimer", G1/03, G2/03*)

- however, at least one non-medical application must have been disclosed
- a claim may not become contradictory in itself by terming an actually excluded medical method as non-therapeutic, non-surgical or non-diagnostic
- indication of undisclosed disclaimer in description

Overview

General Considerations

Diagnostic Methods

Therapy and Surgery: Common Aspects

Surgical Methods

Therapeutic Methods

First and Further Medical Use Protection

Diagnostic Methods (G1/04)

Terminology and definitions:

- (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")
- (i)-(iii): "preceding steps constitutive for making a diagnosis" ("intermediate findings of diagnostic relevance")
- (iv): "diagnosis for curative purposes *stricto sensu*"

Diagnostic Methods (G1/04)

General aspects:

- The general task of the EPO is to grant patents (Art. 4(3) EPC)
- The principle "exclusion clauses are to be construed narrowly" also applies in respect of the scope of the exclusion from patentability under Art. 52(4) EPC 1973 concerning diagnostic methods
- "There is no reason to deviate from the established jurisprudence of the EPO" (i.e. T385/86, T775/92, T530/93, T1165/97, T807/98, ...)

in order to fall under the prohibition of Art. 52(4) EPC 1973, the claim is to include all steps (i), (ii), (iii) and (iv)

Diagnostic Methods (G1/04)

Involvement of medical or veterinary practitioner:

- **diagnostic character may not depend on who is involved** (participation, presence or responsibility med. or vet. practitioner, medicinal or non-medicinal support staff is not decisive)
- legal certainty (no definition possible on a European level, assessment could change considerably in time)
- protection of med. or vet. practitioners could be achieved by enacting legal provisions on the national level of the Contracting States if deemed necessary

Diagnostic Methods (G1/04)

Technicality:

- the deductive decision phase (iv), i.e. the "diagnosis *stricto sensu*" is an intellectual exercise not regarded as an invention under Article 52(1), i.e. non-technical (unless carried out by a device)
- in order to be an "invention" under Art. 52(1), a diagnostic method must necessarily include further preceding technical steps (e.g. (i)-(iii)) in addition to (iv) when non-technical
- a claim including technical and non-technical features may satisfy Art. 52(1) if the non-technical features interact with technical features in order to bring about a technical effect (T603/89)
- comparison phase (ii) "predominantly of non-technical nature"

Diagnostic Methods (G1/04)

"practised on the human or animal body":

- criterion to be considered only in respect of technical steps and must be fulfilled for all technical steps
- step (iv) cannot be practised on the human or animal body
- criterion is satisfied if the performance of the respective step implies any interaction with the human or animal body, necessitating the presence of the latter (a direct physical interaction is not required)

Diagnostic Methods (G1/04)

Essential features:

- if it is constitutive for defining the invention, even a non-technical feature must also be included in the independent claim under Art. 84 taken in combination with Rule 29 EPC 1973 [Rule 43]
- applies to any non-technical preceding step (i)-(iii) as well as to the normally non-technical step (iv) "if its essentialness is unambiguously inferable" from the application as a whole
- this is the case when the intermediate findings of diagnostic relevance "allow the attribution of the detected deviation to a particular clinical picture"

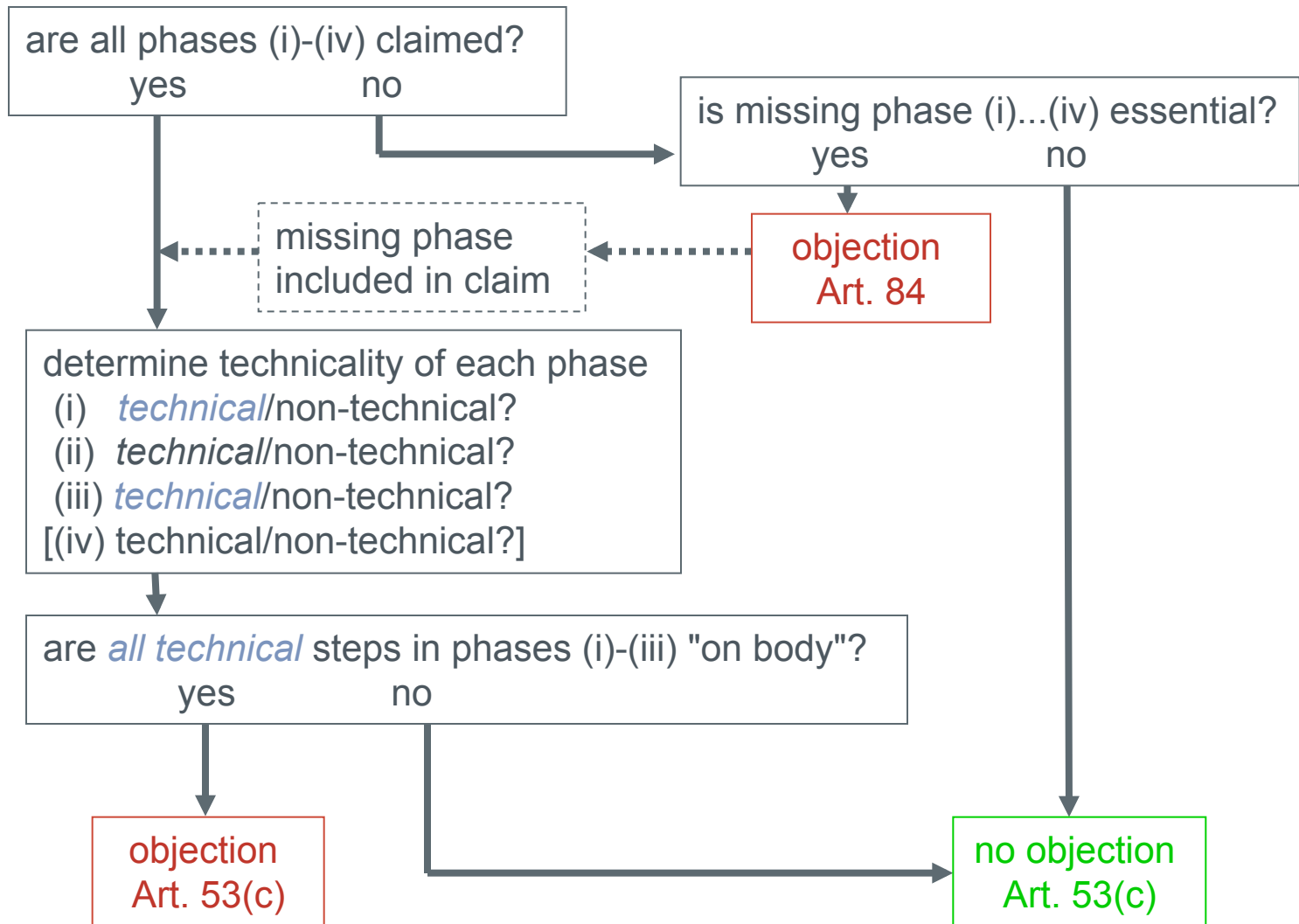
Diagnostic Methods (G1/04)

Devices:

If some or all of the preceding steps (i)-(iii) are carried out by a device without implying any interaction with the human or animal body (e.g. by using a software program), the respective steps do not satisfy the criterion "practised on the human or animal body" (→ not objectionable under Art. 52(4) EPC 1973)

(if diagnostic conclusions are attained by a method not including the use of the device, those carrying it out will not be inhibited by the patent)

Diagnosis



Example of a Non-Diagnostic Method (T330/03)

Claim:

A method for measuring at least one parameter of a sample comprising the steps of:

- (a) illuminating said sample with light;
- (b) performing at least two spectroscopic measurements ...
- (c) analyzing said spectroscopic measurements to determine a measurement of said at least one parameter of said sample.

description: e.g. glucose in blood (in vivo and in vitro)

phases (ii)-(iv) are missing

"provides only intermediate results" → **not a diagnostic method**

Example of a Diagnostic Method (T125/02)

Claims [renumbered]:

1. Method for ascertaining the current lung function of a human subject, comprising the step of
 - measuring the endogenous nitrogen monoxide content ... during one or more exhalation phases in a sample of exhaled air.
2. Method according to claim 1, further comprising the steps of
 - comparing said measured content ... to the endogenous nitrogen monoxide content ... during one or more exhalation phases of a human subject having complete of unimpaired respiratory tract function, and
 - interpreting the deviation manifested by said comparison as an indication of impaired respiratory tract function.

Evaluation of the Respiratory Function (T125/02)

Decision:

examination phase (i):

1. "measuring the endogenous nitrogen monoxide content ..." clearly corresponds to an examination phase and inevitably involves the collection of data
2. measuring is of a **technical** nature
3. the presence of the human subject and the connection to the device is necessary, the condition "practised **on the human body**" is therefore satisfied

Evaluation of the Respiratory Function (T125/02)

Decision:

comparison phase (ii):

1. represented by the feature "comparing said measured content to the content ... of a human subject having complete of unimpaired respiratory tract function"
2. this activity is predominantly of a **non-technical** nature

Evaluation of the Respiratory Function (T125/02)

Decision:

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

1. this step is represented by the feature "**(interpreting) a deviation manifested by said comparison**"
2. this step also has **no technical** character

Evaluation of the Respiratory Function (T125/02)

Decision:

attribution of the deviation to a particular clinical picture
deductive medical or veterinary **decision phase (iv):**

1. **"interpreting (the deviation) as an indication of impaired respiratory tract (or lung) function"**
 - represents the determination of the nature of a medical condition
 - provides an understanding of the specific metabolic disorder in the lungs
 - sufficient to decide upon a therapeutic action to be taken (curative purpose of diagnosis)
- last step of the claimed method can be regarded as the attribution of the deviation to a particular clinical picture
- diagnostic method prohibited by Art. 52(4) EPC 1973

Evaluation of the Respiratory Function (T125/02)

1. Method for ascertaining the current lung function of a human subject, comprising the step of
 - measuring the endogenous nitrogen monoxide content ... during one or more exhalation phases in a sample of exhaled air. (i)
2. Method according to claim 1, further comprising the steps of
 - comparing said measured content ... to the endogenous nitrogen monoxide content ... during one or more exhalation phases of a human subject having complete of unimpaired respiratory tract function, and (ii)
 - interpreting the deviation manifested by said comparison as an indication of impaired respiratory tract function. (iii)
(iv)

Evaluation of the Respiratory Function (T125/02)

Summary:

- steps of all four phases (i)-(iv) are present
 - steps of phases (ii) and (iii) are non-technical
 - steps of phase (i) are technical and performed on the human body
- all technical steps in phases (i)-(iii) are performed on the body
- diagnostic method according to G1/04

Diagnostic Methods

Points to note:

- phase (iii) may be implicit (T1197/02)
- phases (ii)-(iv) may also be comprised in dependent claims (not necessarily in independent claim; T125/02)
- phase (iv) does not require the definition of a specific disease (T125/02, T1197/02)
- intermediate/additional steps not strictly forming part of phases (i)-(iv) are left aside when assessing diagnostic character (T125/02, T143/04)
- phases (ii) and (iii) are "predominantly/principally" not technical "in most cases" (T125/02, T1197/02)

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Surgery and Therapy

Definition of the term "medical treatment" in T182/90:

any non-insignificant intentional physical or psychic intervention performed directly or indirectly by one human being - who need not necessarily be a medical practitioner - on another (or, by analogy, on animals) using means or methods of medical science

may also include treatments for non-curative purposes:

- cosmetic treatment
- castration
- artificial insemination
- treatments for experimental and research purposes
- removal of organs, skin or bone marrow from a living donor
- termination of pregnancy
- sterilisation
- embryo transplants

Surgery and Therapy - The Single Step Criterion

Guidelines C-IV, 4.8.1:

a method claim is not allowable under Art. 53(c) if it includes **at least one feature** defining a physical activity or action that constitutes a method step for treatment of the human or animal body by **surgery** or **therapy**. In that case, whether or not the claim includes or consists of features directed to a technical operation performed on a technical object is legally irrelevant to the application of Art. 53(c)

G1/04:

"... the surgical or therapeutic nature of a method claim can perfectly be established by a single method step ..."

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Therapy - Definitions and Criteria

1. **curative** therapy:

healing or curing of diseases, illnesses, malfunctions, disorders, injuries (T19/86)

2. **symptomatic** therapy:

relief of pain, discomfort or incapacity, even if of natural origin, e.g. due to menstruation or pregnancy (T81/84, T24/91, T443/01)

3. **prophylactic** therapy:

vaccination (T19/86), immunostimulation (T780/89), removal of plaque (T290/86)

Therapy - Functional Link

Guidelines C-IV, 4.8.1:

A method for therapeutic purposes concerning the functioning of an apparatus associated with a living human or animal body is **not excluded** from patentability **if no functional relationship** exists between the steps related to the apparatus and the therapeutic effect of the apparatus on the body (see T245/87)

no functional link:

- no physical causality between method steps and therapeutic effect
- **not objectionable as therapeutic**

Therapy - Dialysis

Guidelines C-IV, 4.8.1:

Treatment of body tissues or fluids after they have been removed from the human or animal body, or diagnostic methods applied thereon, are not excluded from patentability **insofar as these tissues or fluids are not returned to the same body.**

Thus the treatment of blood for storage in a blood bank or diagnostic testing of blood samples is not excluded, whereas a **treatment of blood by dialysis** with the blood being returned to the same body would be **excluded.**

Therapeutic and Non-Therapeutic Indications

Some methods may have **both** therapeutic **and** non-therapeutic applications, e.g.

- cosmetic applications
- athletic training
- agriculture

as long as therapeutic aspects are covered, the method is regarded as therapeutic and not patentable

e.g. cosmetic treatment involving therapy (or surgery)

(Guidelines C-IV, 4.8.1)

Therapeutic and Non-Therapeutic Indications

Exclusion can be avoided if the following conditions are fulfilled:

1. non-therapeutic and therapeutic effects are **clearly distinguishable** (not inextricably linked) and
 2. claim is **limited to the non-therapeutic** application(s)
- not objectionable under Art. 53(c)

it is not possible to overcome the prohibition by a **purely formal rewording** of the claim, so as to qualify the purpose of the process as non-therapeutic (e.g. cosmetic) (T1077/93)

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First Medical Use

Art. 54(4) EPC (cf. Art. 54(5) EPC 1973):

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.

- "product-for-purpose" claim (e.g. "substance X for use as a medicament/for curing disease Y")
- broad protection for an important contribution (opens the field of medical use for a known substance or composition)
- exception to the concept of absolute novelty
- only available for "first" application of a substance in medicine

Second or Further Medical Use

Art. 54(5) EPC:

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.

- provides protection for any second or further use in medicine (if it is new and inventive: e.g. AspirinTM, known as a pain killer, subsequently also found to prevent blood clots)
- **not** available for **apparatus/devices** (T227/91, T775/97, T1172/03)
- available for applications filed \geq 13.12.07, or pending at that time as far as decision to grant not yet handed over to internal post
- obviates the need for the "Swiss-type" claim formulation (G5/83)

Thank you for your attention

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