

# Learning path for patent examiners

## Patentability: exceptions and exclusions: Intermediate level

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## Introduction

This publication, "Patentability: exceptions and exclusions, Intermediate level", is part of the "Learning path for patent examiners" series edited and published by the European Patent Academy. The series is intended for patent examiners at national patent offices who are taking part in training organised by the European Patent Office (EPO). It is also freely available to the public for independent learning.

Topics covered include novelty, inventive step, clarity, unity of invention, sufficiency of disclosure, amendments and search. Also addressed are patenting issues specific to certain technical fields:

- patentability exceptions and exclusions in biotechnology
- assessment of novelty, inventive step, clarity, sufficiency of disclosure and unity of invention for chemical inventions
- the patentability of computer-implemented inventions, business methods, game rules, mathematics and its applications, presentations of information, graphical user interfaces and programs for computers
- claim formulation for computer-implemented inventions

Each publication focuses on one topic at entry, intermediate or advanced level. The explanations and examples are based on the European Patent Convention, the Guidelines for Examination in the EPO and selected decisions of the EPO's boards of appeal. References are made to the Patent Cooperation Treaty and its Regulations whenever appropriate.

The series will be revised annually to ensure it remains up to date.

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## 1. Learning objectives

Participants to this course will learn:

- The definition and legal basis of the exceptions to patentability regarding essentially biological processes for the production of plants or animals and plants or animals thereof.
- The patentability of the human body and its parts.
- The legal basis behind the patentability of transgenic organisms
- The concepts of methods of treatment and diagnosis.

## 2. Essentially biological processes for producing plants or animals

Article 53(b) EPC states: "European patents shall not be granted in respect of plant or animal varieties or essentially biological processes for the production of plants or animals; this provision shall not apply to microbiological processes or the products thereof".

Rule 26(5) EPC further stipulates that a process for producing plants or animals which is based on the sexual crossing of whole genomes and on the subsequent selection of plants or animals is excluded from patentability for being essentially biological.

This applies even if the process involves human intervention, including providing technical means, serving to enable or assist the performance of the process steps, or if the claims contain any other technical steps relating to the preparation of the plant or animal or its further treatment before or after the crossing and selection steps (see G 1/08 and G 2/07).

Genetic engineering techniques applied to plants, which differ profoundly from conventional breeding techniques as they work primarily through the purposeful insertion and/or modification of one or more genes in a plant, are patentable (see T 356/93). However, the claims in these cases must not, either explicitly or implicitly, include the sexual crossing and selection process.

### Examples

A method of crossing, interbreeding or selectively breeding horses (for example), involving merely selecting for breeding animals (or their gametes) having certain characteristics and bringing those animals (or gametes) together would be essentially biological and therefore excluded from patentability.

### Legal references:

Art. 53(b) EPC, GL G-II, 5.4, G 2/07, G 1/08, T 356/93

## 3. Plants or animals produced by essentially biological processes

Rule 28(2) EPC excludes products (plants/animals and plant/animal parts) exclusively obtained by non-technical, i.e. essentially biological, processes.

The exclusion extends to plants and animals exclusively obtained by means of an essentially biological process where there is no direct technical intervention in the genome of the plants or animals as the relevant parental plants or animals are merely crossed and the desired offspring selected. This is the case even if technical means are provided, serving to enable or assist the

performance of the essentially biological steps. In contrast, plants or animals produced by a technical process which modifies the genetic characteristics of the plant or animal are patentable.

The term "exclusively" is used here to mean that a plant or animal originating from a technical process or characterised by a technical intervention in the genome is not covered by the exclusion from patentability, even if a non-technical method (crossing and selection) is additionally applied during its production.

Determining whether a plant or animal is obtained by exclusively biological means entails examining whether there is a change in a heritable characteristic of the claimed organism as a result of a technical process going beyond mere crossing and selection, i.e. not merely serving to enable or assist the performance of the essentially biological process steps.

Transgenic plants and mutants induced by technical means are thus patentable, while the products of conventional breeding are not.

This exclusion regarding plants and animals exclusively obtained by means of an essentially biological process applies to patent applications with a filing date and/or a priority date after 1 July 2017. It does not apply to patents granted before that date or to pending patent applications with a filing date and/or a priority date before 1 July 2017 (see [G.3/19](#)).

### Examples

- A plant produced by introgression of gene A, i.e. by introducing it into the genome by crossing and selection.
- A plant produced exclusively by crossing and selection, wherein molecular markers are used to assist the selection process.
- A plant part obtained exclusively by means of an essentially biological process which is propagation material, e.g. a seed or plant embryo.
- A cultivated pepper expressing a mutant AHAS enzyme.

### Legal references:

[R. 28\(2\) EPC](#), [GL G-II, 5.4](#), [G 3/19](#)

## 4. Definition of plant variety

[Article 53\(b\) EPC](#) states: "European patents shall not be granted in respect of plants or animal varieties or essentially biological processes for the production of plants or animals; this provision shall not apply to microbiological processes or the products thereof".

The Community Plant Variety Office is responsible for the protection of plant varieties:  
<https://cpvo.europa.eu/en>

A patent is not to be granted if the claimed subject-matter is directed to a specific plant variety or specific plant varieties.

**Rule 26(4) EPC** defines the term "plant variety" as follows:

"(4) 'Plant variety' means any plant grouping within a single botanical taxon of the lowest known rank, which grouping, irrespective of whether the conditions for the grant of a plant variety right are fully met, can be:

- a. defined by the expression of the characteristics that results from a given genotype or combination of genotypes,
- b. distinguished from any other plant grouping by the expression of at least one of the said characteristics, and
- c. considered as a unit with regard to its suitability for being propagated unchanged."

The method for producing the plant, be it by recombinant gene technology or by a classical plant breeding process, is irrelevant for considering this issue (see T.1854/07). Therefore, plant varieties containing genes introduced into an ancestral plant by recombinant gene technology are excluded from patentability (G.1/98).

However, if the invention concerns plants or animals which are not exclusively obtained by means of an essentially biological process (see G.3/19), and if the technical feasibility of the invention is not confined to a particular plant or animal variety, the invention is patentable (see Guidelines G-II.5.2).

A claimed plant grouping is not excluded from patentability under Article 53(b) EPC if it does not meet the definition of a plant variety set out in Rule 26(4) EPC.

When examining a claim to a process for producing a plant variety, Article 64(2) EPC is not to be taken into consideration (see G.1/98). Hence, a process claim for producing a plant variety (or plant varieties) that is not exclusively essentially biological is not *a priori* excluded from patentability merely because the resulting product constitutes or may constitute a plant variety.

Controlled hybrids with inbred parents are excluded from patentability under Article 53(b) EPC as they define either a seed or a plant which necessarily belongs to a particular plant grouping as per the definition of "plant variety" pursuant to Rule 26(4) EPC.

A claim cannot escape the exclusion of plant varieties under Article 53(b) EPC by consisting of a large number of varieties, not even if there are hundreds of them. Only if the subject-matter of the claim includes at least one embodiment which does not constitute a variety is the claim allowable under Article 53(b) EPC (see T.1208/12).

### Examples

- A claim directed to a hybrid of a specific deposited Brassica variety with any high-yielding Brassica variety results in a Brassica hybrid variety, which is not patentable.
- A plant variety such as durum wheat type wh222 deposited at a seed depositary does not comply with Article 53(b) EPC.
- A transgenic plant and its seeds containing an exogenous bacterial gene encoding Bt toxin is technically not limited to one variety and, although it may encompass varieties, it complies with Article 53(b) EPC.

## Legal references:

R. 26(4) EPC, GL G-II, 5.4.1

## 5. Patentability of the human body and its parts

Although the human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions (see Rule 29(1) EPC and Guidelines G-II, 5.3), an element isolated from the human body or otherwise produced by means of a technical process and which is susceptible of industrial application, including the sequence or partial sequence of a gene, may constitute a patentable invention even if the structure of that element is identical to that of a natural element.

Any such element is not *a priori* excluded from patentability since it is, for example, the result of technical processes used to identify, purify and classify it and produce it outside the human body – techniques which human beings alone are capable of putting into practice and which nature is incapable of accomplishing itself.

Regarding the patentability of the human body and its elements, the EPC adheres to European Union Directive 98/44/EC on biotechnological inventions, in particular the following recitals:

- Recital 17: significant progress in the treatment of diseases has been made thanks to said elements; research aimed at obtaining and isolating such elements for medicinal production should be encouraged
- Recital 20: element isolated and susceptible of industrial application; the rights conferred by the patent do not extend to the human body and its elements in their natural environment
- Recital 21: technical process used to identify, purify, classify and reproduce the element
- Recital 26: informed consent from the person from which the element was isolated, in accordance with national law

## Legal references:

Art. 53(a) EPC, R. 29 EPC, GL G-II, 5.2, GL G-II, 5.3, EU Directive 98/44/EC

## 6. Patentability of transgenic organisms

Transgenic plants and animals fall under the patentable biotechnological inventions of Rule 27(b) EPC.

- Rule 27(b) EPC states that biotechnological inventions comprising plants or animals may be patentable if the technical feasibility of the invention is not confined to a particular plant or animal variety and if said plants or animals are not exclusively obtained by means of an essentially biological process (Rule 28(2) EPC).

Inventions which concern plants or animals are patentable if the application of the invention is not technically confined to a single plant or animal variety (Directive 98/44/EC, recital 29). However, said plants or animals must not be exclusively obtained by means of an essentially biological process (see Guidelines G-II, 5.4).

- The subject-matter of a claim that covers but does not identify plant varieties is not a claim to a variety or varieties (see G 1/98, Reasons 3.8). In the absence of the identification of a specific

plant variety in a product claim, the subject-matter of the claimed invention is neither limited nor directed to a variety or varieties within the meaning of [Article 53\(b\) EPC](#) ([G 1/98](#), Reasons 3.1 and 3.10) and therefore is not excluded from patentability.

- Reason 3.10: "In the absence of the identification of a specific plant variety in a product claim, the subject-matter of the claimed invention is not directed to a plant variety or varieties within the meaning of [Article 53\(b\) EPC](#). This is why it is, contrary to the conclusions of the referring Board, in agreement with the rules of logic that a patent shall not be granted for a single plant variety but can be granted if varieties may fall within the scope of its claims."
- Reason 3.8: "Providing these tools is a step which precedes the further step of introducing the gene into a specific plant. Nevertheless, it is the contribution of the inventor in the genetic field which makes it possible to take the second step and insert the gene into the genome of any appropriate plant or plant variety. Choosing a suitable plant for this purpose and arriving at a specific, marketable product, which will mostly be a plant variety, is a matter of routine breeding steps which may be rewarded by a plant breeders' right. The inventor in the genetic engineering field would not obtain appropriate protection if he were restricted to specific varieties for two reasons: first, the development of specific varieties will often not be in his field of activity and, second, he would always be limited to a few varieties even though he had provided the means for inserting the gene into all appropriate plants."

## Examples

"A plant variety such as durum wheat type wh222 deposited at a seed depositary."

"A transgenic plant and its seeds containing an exogenous bacterial gene encoding Bt toxin."

The first claim is directed and limited to a plant variety (not patentable) whereas the subject-matter of the second claim can be applied to plants in general and thus complies with [Article 53\(b\) EPC](#).

## Legal references:

[Art. 53\(b\) EPC](#), [Art. 83 EPC](#), [R. 27\(b\) EPC](#), [R. 28\(1\) EPC](#), [G 1/98](#)

## 7. Methods of treatment by therapy

The concept of therapy is any treatment designed to cure, alleviate, remove or lessen the symptoms of a disorder or malfunction of the human or animal body:

- **curative** therapy, such as healing or curing of diseases, illnesses, malfunctions, disorders, injuries ([T 19/86](#))
- **symptomatic** therapy of a disease or relief of pain, discomfort or incapacity, even if of natural origin, e.g. due to menstruation or pregnancy ([T 81/84](#), [T 24/91](#), [T 443/01](#))
- **prophylactic** therapy, such as vaccination ([T 19/86](#)), immunostimulation ([T 780/89](#)), removal of plaque ([T 290/86](#))

The exclusion under [Article 53\(c\) EPC](#) also applies to multi-step methods which comprise or encompass **at least one therapeutic step**, even if this step is only implicit ([G 1/07](#); [T 1005/98](#)). The non-patentable subject-matter must be removed from the scope of the claim. This may be done either by means of a disclaimer or by omitting the step of treatment by therapy from the wording of the claim ([G 1/07](#)). For the general principles governing disclaimers, see Guidelines [H-V. 4.1](#) and [H-V. 4](#). The overall patentability of the amended claim will, however, depend on its compliance with the other requirements of the EPC, which are assessed on a case-by-case basis.



## Legal references:

Art. 53(c) EPC, GL G-II, 4.2.1.2; GL H-V, 4.1; GL H-V, 4 CL Book I.B.4.4, G 1/07, T 1005/98

## 8. Methods of treatment by surgery

There is no general definition of surgery that is applicable to every technical circumstance. As the relevant case law since G 1/07 is not consistent, some borderline cases have been identified that might be considered surgical under some decisions but not others. Careful consideration is required in this respect as it is impossible to definitively say how to treat each and every situation that may arise. Whether a claimed method is to be considered a surgical treatment falling under the exception of Article 53(c) EPC should be assessed on a **case-by-case** basis.

For determining whether a claim is directed to a surgical method within the meaning of Article 53(c) EPC and thus excluded from patentability, please refer to the Guidelines G-II, 4.2.1.1, and G 1/07.

Methods or steps not regarded as surgical within the meaning of Article 53(c) EPC are those which are considered to involve a low risk when carried out with the required medical care and expertise and to be a routine minor intervention.

In contrast, steps considered excluded are physical interventions on the body which take place in a medical environment, **require professional medical skills** and **involve substantial health risks** even when carried out with the required medical professional care and expertise (e.g. guiding a catheter). It does **not** matter whether the method **is computer-implemented, robot-performed or human-performed**.

Methods of collecting data *in vivo* or imaging may include a surgical step that has to be objected to under Article 53(c) EPC. The nature of the contrast agent is irrelevant for the issue of assessing whether the claimed method is to be excluded from patentability as a surgical method pursuant to Article 53(c) EPC (see G 1/07).

Methods that are non-surgical (and thus allowable under Article 53(c) EPC) are uncritical methods involving only a minor intervention with no substantial health risk (e.g. tattooing, piercing, hair removal by optical radiation and micro-abrasion of the skin).

It is important to note that the term "surgery" defines the **nature of the treatment rather than its purpose**. For example, a method of treatment by **surgery for cosmetic purposes or for embryo transfer is excluded from patentability**, as is surgical treatment for therapeutic purposes.

Allowable	Excluded
Tattooing, piercing Hair removal by optical radiation Micro-abrasion of skin	Conservative methods Lumbar puncture, opening of bodily cavities, excision, etc.
<b>Decisions subsequent to G 1/07</b>	
... producing an MR angiogram ... wherein a contrast <b>agent</b> has <b>previously</b> been <b>introduced</b> (T 266/07)	(Injection into the heart T 992/03) process for measuring the rate of blood flow in a shunt (T 1695/07) → "more abstract risk criterion"/medical practitioner ≠ medical doctor
Injecting a contrast agent into a vein remote from the artery (T 663/02), risk matrix as criterion/ <u>delegatibility</u>	Venipuncture and withdrawal of blood (T 1075/06)

## Legal references:

Art. 53 (c) EPC, GL G-II, 4.2.1.1, CL Book I.B.4.3, G 1/07

## 9. Diagnostic methods

To determine whether a claim is directed to a diagnostic method within the meaning of **Article 53(c) EPC** and thus excluded from patentability, it must first be established whether the claim includes steps relating to all the necessary phases (Guidelines G-II, 4.2.1.3; G 1/04), i.e. the following:

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

All phases (i)-(iv) have to be present at least implicitly in the claim. A reference to said steps in the description (either explicitly or implicitly) is sufficient.

The method is only regarded as a diagnostic method if all **method steps of a technical nature** belonging to the preceding steps which are constitutive for making the diagnosis **satisfy the criterion of "practised on the living human or animal body"** (post-mortem not included).

It is implicit that this criterion does not apply to phase (iv) (attribution of deviation to a particular clinical picture), i.e. the deductive medical or veterinary decision phase.

The steps of phases (ii) and (iii), which involve comparing the data collected in the examination phase with standard values and finding a significant deviation resulting from the comparison, are not subject to this criterion because these activities are predominantly of a non-technical nature and are normally not practised on the human or animal body.

Therefore, in most cases only phase (i), which refers to the examination phase and involves collecting data, can actually be of a technical nature within the meaning of G 1/04 and, therefore, concerned with the criterion "practised on the human or animal body". A direct physical interaction with the body is not necessary.

Examples:

- Acquiring data from *in vitro* samples does not qualify as "practised on the human or animal body" (phase (i) is present but not practised on the body).
- Taking an X-ray image of a patient without physical contact between the X-ray apparatus and the patient qualifies as "practised on the human or animal body" as long as the presence of the patient is necessary for phase (i).

The deductive medical or veterinary decision phase (iv), i.e. the "diagnosis for curative purposes *stricto sensu*", is the determination of the nature of a medical or veterinary medical condition **intended to identify or uncover a pathology**; it is not necessary to identify the underlying disease (see T 125/02).

If features pertaining to any of phases (i)-(iv) are missing and are essential for the definition of the invention, those features are to be included in the independent claim.

Some applicants may try to overcome the objection under Article 53(c) EPC by deleting one of phases (i)-(iv); this is only allowable if the omitted step is not described as being essential for the definition of the invention.

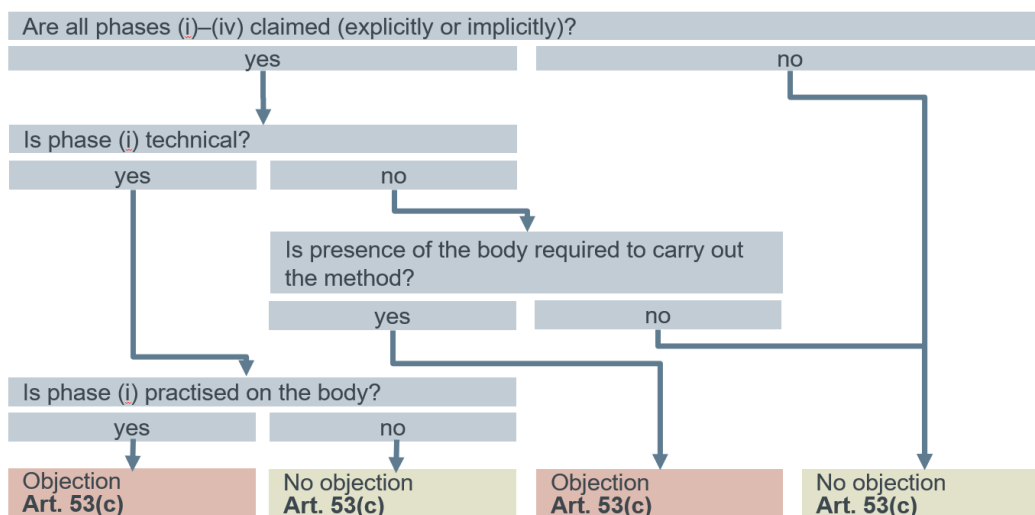
Note that an objection as to lack of essential features cannot be raised merely because phase (iv) has not been claimed, since the method might just relate to a measuring method and be limited to steps (i)-(iii). In certain cases, however, it may be apparent from the description that phase (iv) is in fact essential for carrying out the invention and cannot be omitted; in that case, an objection under Article 84 EPC can be raised.

For reasons of legal certainty, the grant procedure may not be rendered dependent on the involvement of the medical or veterinary practitioner, i.e. an activity cannot be deemed to have a diagnostic character depending on who is involved. Accordingly, the participation, presence or responsibility of the practitioner is not decisive. It is also irrelevant whether the method could also – or only – be practised by medical or non-medical support staff, the patient themselves or an automated system.

Some further important points to note:

- **Phase (iii) may be implicit** (T.1197/02).
- **Phases (ii)-(iv) may also be found in dependent claims** (not necessarily in the independent claim; T.125/02).
- **Phase (iv) does not require a specific disease** to be specified (T.125/02, T.1197/02).
- **Intermediate/additional** steps not strictly forming part of phases (i)-(iv) are **left aside** when **assessing diagnostic** character (T.125/02, T.143/04).

This is the basic flowchart for determining if a method is to be considered diagnostic as per Article 53(c) EPC:



**Note 1:** if data are acquired e.g. from a database, there is no phase (i) as per G.1/04, so not all phases (i)-(iv) are present.

**Note 2:** phase (i) can be non-technical, e.g. visual observation of the patient by the doctor, yet the claim can still be technical if some of the intermediate steps in the claim are technical (e.g. using a computer).

- If phase (i) is not technical and the claimed method does not include any step practised on the human or animal body, then the method does not fall under the exception of Article 53(c) EPC because it does not fulfil the criterion specified in that article of "practised on the human or animal body".
- If phase (i) is not technical and the claimed method requires the presence of the body (e.g. visual observation of the patient by the doctor; the patient is present), then the method still falls under the exception of Article 53(c) EPC.

This is not directly derivable from the wording of the Guidelines but is based directly on Article 53(c) EPC. It is the reason for the condition in the box in the middle of the slide ("Is presence of the body required to carry out the method?").

**Note 3:** "visual observation of the patient by the doctor" (e.g. to determine dermatitis) qualifies as "practised on the human or animal body".

An example case of a diagnostic method is T 125/02:

### Case T 125/02

Method for ascertaining the current lung function of a human subject by...

- measuring endogenous NO content ... in a sample of exhaled air.
- comparing said measured content... to endogenous NO content ... of a human subject having complete or unimpaired respiratory tract function
- interpreting a deviation manifested by said comparison as an indication of impaired respiratory tract function.

Phase	technical	on body
i)	yes	yes
ii)	no	
iii)	no	
iv)	no	

### Summary of T 125/02:

- Steps of **all four phases** (i)-(iv) are **present**.
- Steps of phases **(ii), (iii) and (iv) 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** as per G 1/04 and excluded under Article 53(c) EPC.

**Legal references:**

Art. 53 (c) EPC, GL G-II, 4.2.1.3, G 1/04, CL Book I.B.4.5

**10. Beyond the course**

You can deepen what you have learned during this course with the following further readings:

- Further reading 1: G 3/19
- Further reading 2: T 144/83, T 74/93, T 19/86, T 290/86, T 820/92, T 74/93

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European Patent Office  
Munich  
Germany  
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Responsible for the content  
European Patent Academy  
[academy@epo.org](mailto:academy@epo.org)