

# Learning path for patent examiners

## Assessment of novelty: chemical inventions: Intermediate level

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## Introduction

This publication, "Assessment of novelty: chemical inventions, 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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## Contents

1. Learning objectives	5
2. Novelty of stereoisomeric forms	5
3. Novelty by purity	6
4. Implicit functional features	6
5. Two-list principle, applied to chemical/Markush formulae	7
6. Novelty of sub-set selections, applied to Markush formulae	8
7. Novelty of chemical ranges	9
8. Products by process	11
9. Enabling disclosure – hits in databases	12
10. Enabling disclosure – undisclosed synthesis	13
11. First medical use – claim format	14
12. Second medical use – claim format	15
13. Second medical use – claim format for dependent claims	16
14. Swiss-type claims	17
15. Non-allowable medical claim formats	17
16. Diagnostic and surgical uses pursuant to Article 54(5) EPC	18
17. Characterising features in second medical use claims: groups of patients	20
18. Characterising features in second medical use claims: route of administration	21
19. Substance or composition as per Article 54(4) and (5) EPC	21
20. Difference between substance/composition under Article 54(4) and (5) EPC and a medical device	22
21. Beyond the course	25

## Legal references

Art. 54 EPC, CL Book I.C.6.2.3, T 296/87, T 1760/11	5
Art. 54 EPC, GL G-VI, 6, T 1085/13, T 1617/10	6
Art. 54 EPC, GL G-VI, 5	7
Art. 54 EPC, GL G-VI, 7, T 12/81	8
Art. 54 EPC, GL G-VI, 7	9
Art. 54 EPC, GL G-VII, 8, T 175/97, CL Book I.C.6.3, I.C.6.3.2	9
Art. 54 EPC, GL G-VII, 8(iii), CL Book I.C.6.3.2, T 666/89, T 26/85	10
Art. 54 EPC, GL G-VII, 8(ii), CL Book I.C.6.3.1, T 261/15, T 279/89	11
Art. 54 EPC, GL F-IV, 4.12, CL Book II.A.7.6	12
Art. 54 EPC, GL G-IV, 2, CL Book II.A.7.6	13
Art. 54 EPC, T 206/83, OJ 1987, 5	14
Art. 53(c) EPC, Art. 54(4) EPC, GL G-VI, 6.1, T 1099/09, T 1069/11, T 1578/15	15
Art. 54(5) EPC, GL G-VI, 6.1.1, GL G-VI, 6.1.2, G 2/08, T 241/95, T 830/08	16
Art. 84 EPC, Art. 54(5) EPC, GL G-VI, 6.1.5	17
Art. 54(5) EPC, G 2/08, G 5/83	17
Art. 54(4) EPC, Art. 54(5) EPC, Art. 53(c) EPC, GL G-VI, 6.1.2	18
Art. 53(c) EPC, Art. 54(5) EPC, GL G-VI, 6.1, GL G-VI, 6.1.4, G 1/07, G 1/04, CL Book I.B.4.5.1	19
Art. 53(c) EPC, Art. 54(5) EPC, CL Book I.C.7.2.4, T 734/12	21
Art. 53(c) EPC, Art. 54(5) EPC, CL Book I.C.7.2.4	21
Art. 54(4) EPC, Art. 54(5) EPC, GL G-VI, 6.1.1, T 1758/15	22
Art. 54(4), (5) EPC, CL Book I.C.7.2.4 g), G 5/83	24
Art. 54(4) EPC, Art. 54(5) EPC, CL Book I.C.7.2.4 g), G 5/83	25

## 1. Learning objectives

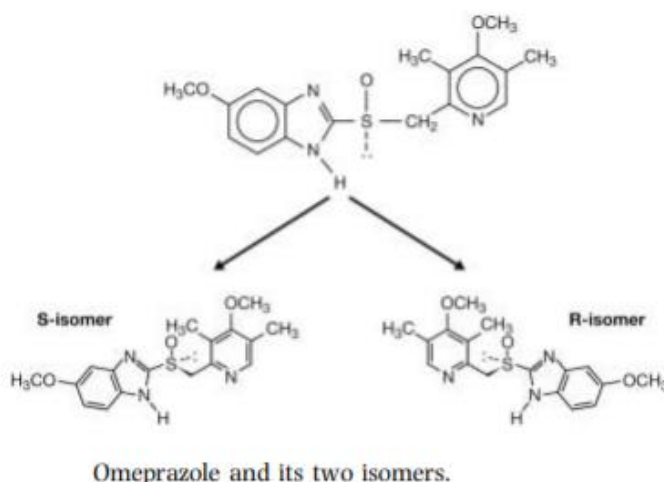
Participants to this course will learn:

- The fundamentals of novelty assessment for chemical compounds, formulations, ranges and product-by-process claims
- The definition and the legal basis of an enabling disclosure for chemical compounds
- The principle of medical use claims (therapy, diagnosis, surgery)

## 2. Novelty of stereoisomeric forms

A chemical compound may be novel over another having the same molecular formula but different stereospecificity. Chiral compounds can form enantiomers. They have the same formula and structure but different stereospecificity. One particular stereoisomer can be novel over the other (e.g. S-enantiomer over R-enantiomer). A specific enantiomer may be novel over the racemic form.

### Examples



The chemical formula above shows omeprazole, a highly successful medication against excessive gastric acid. Omeprazole has a stereocenter at the sulfur atom.

The lone electron pair on the sulfoxide indicated above by ":" is directed towards one corner of a tetrahedron. Thus, the situation is the same as for a chiral carbon atom.

The molecule can exist in the racemic form, as the S- or R-isomer. Initially, a patent was filed disclosing the racemic form, followed later by a patent for the more active S-enantiomer. The disclosure of the racemic form was not considered novelty-destroying for the later-filed patent for the S-enantiomer.

### Legal references:

Art. 54 EPC, CL Book I.C.6.2.3, T 296/87, T 1760/11

### 3. Novelty by purity

A claim defining a compound as having a certain purity lacks novelty over a prior-art disclosure describing the same compound only if the prior art discloses the claimed purity at least implicitly, for example by way of a method for preparing said compound, the method inevitably resulting in the purity as claimed (Guidelines G-VI, 7, T 1085/13). Such a claim, however, does not lack novelty if the disclosure of the prior art needs to be supplemented, for example by suitable (further) purification methods allowing the skilled person to arrive at the claimed purity.

In another BoA decision (T 1617/10), it was ruled that the probability of the presence of an impurity in a prior-art composition does not take away the novelty of a claim to that composition in which the compound is purposively part of the composition. It was not the probability that was relevant, but rather whether the impurity was inevitably present.

#### Examples

**Example of a claim relating to purity:** "Amorphous Lercanidipine HCl having a purity  $\geq$  99.5% determined by HPLC analysis and containing  $<$  0.5% of crystalline Lercanidipine HCl."

Here, the claim relates to the purity of the solid-state form, and the degree to which the amorphous form is "contaminated" with a crystalline form.

#### Legal references:

Art. 54 EPC, GL G-VI, 6, T 1085/13, T 1617/10

### 4. Implicit functional features

When checking whether features of a claim are anticipated by a prior-art disclosure, what counts are not only apparent or mentioned features, but "implicit" features too.

"Implicit" features are those that are not explicitly mentioned but are present if the skilled person follows the instructions of the prior-art document, i.e. features at which the skilled person would inevitably arrive when following the prior art.

The issue of "implicit feature disclosure" frequently occurs when claims define the invention using a parametric definition but the prior art discloses the same subject-matter with a different parameter or without any parameter at all. The question is then whether this parameter is not obtained in the prior art even if it has not been mentioned – in other words, whether the parameter is "implicitly present".

For the novelty assessment, the following logic applies. If the known and the claimed products are identical in all respects other than a disputed "implicit feature", an objection of lack of novelty is raised. The burden of proof for an alleged distinguishing feature lies with the applicant.

The applicant cannot be given the benefit of the doubt if it does not provide evidence in support of the allegations (T 1764/06).

## Examples

Example of an implicit feature:

Company A claimed processes for preparing baked goods using an enzyme to generate an emulsifier and a second functional ingredient, such as a fatty acid ester, the enzyme being subsequently deactivated during the baking process.

The prior art disclosed a process for preparing baked goods using an enzyme which inherently possessed dual phospholipase/lipase activity for baking bread – although this dual activity was not explicitly disclosed. It was argued that the prior-art process inevitably resulted in an emulsifier and a second functional ingredient by way of the dual enzyme activity, thus anticipating the claimed process.

The inevitable generation of an emulsifier and a further ingredient was considered an "implicit disclosure".

### Legal references:

Art. 54 EPC, GL G-VI, 5

## 5. Two-list principle, applied to chemical/Markush formulae

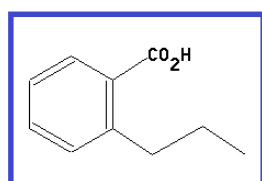
If the prior art does not disclose the claimed subject-matter as a discrete disclosure but does disclose it as the result of combining a body of features with a further feature presented with alternatives in a single list, then this subject-matter is considered novelty-destroying. This applies even if the result of the selection from the single list has not been explicitly described as such. This is called the "single-list principle".

The situation is different if a selection from two different lists is required when construing the novelty-anticipating subject-matter. In that case, there is no discrete disclosure and the result of a twofold selection does not take away novelty either. This is called the "two-list principle".

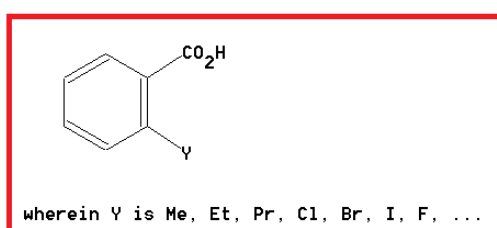
A selection from two or more lists of a certain length resulting in a combination of features confers novelty if the prior art does not disclose any such specific selection.

If a selection from two generic lists is required in order to arrive at the claimed subject-matter, then the generic disclosure is not novelty-destroying.

If the selection has to be made from a one-dimensional list, then even the generic prior-art disclosure (i.e. without a specific example) is considered novelty-destroying.

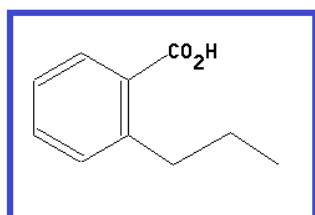


claimed

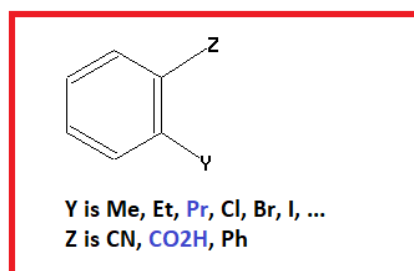


prior art disclosure

In the above case, the claimed compound (blue box) results from a single selection from the prior-art disclosure (red box); the ortho-propyl-benzoic acid is disclosed in the prior art not as a discrete compound but as a result of a "single-list selection".



claimed



disclosed

In the second case, the claimed compound (blue box) is novel over the generic disclosure (red box) as arriving at it would require selections from two lists (choice of Z = CO<sub>2</sub>H and Y = Pr). The generic disclosure of the prior-art Markush formula (red box) is not novelty-destroying.

Prior-art formula "metal halogenide"  
With "metal" = Na, K, Fe, Co, Ni, etc.



Selection "NaCl" would be novel  
Two-dimensional (or more) list

Prior-art formula "metal chloride"  
With "metal" = Na, K, Fe, Co, Ni, etc.



Selection "NaCl" would not be novel  
One-dimensional list

### Legal references:

Art. 54 EPC, GL G-VI, 7, T 12/81

## 6. Novelty of sub-set selections, applied to Markush formulae

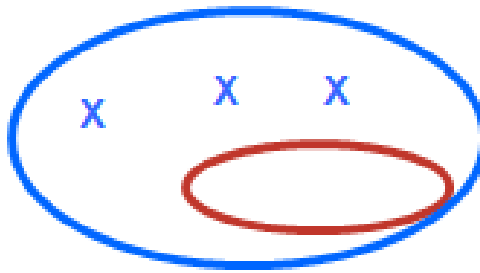
A sub-set of a Markush formula or a (chemical) range can be novel over the prior-art Markush formula/range, provided that:

- there are no examples in the overlapping range
- the overlap is not so substantial that the skilled person would seriously consider working in the area of overlap

### Examples

Let us assume that a Markush formula claims the structural space indicated by the red circle. This red circle lies within the scope of a prior-art Markush formula (blue circle). The red circle describes "a sub-set" of the prior-art structural space.

In the case below, the Markush formula having the scope of the red circle is novel over the prior-art Markush formula describing the blue circle since there are no discrete disclosures (marked as "X") in the claimed sub-set.



**Legal references:**  
Art. 54 EPC, GL G-VI, 7

## 7. Novelty of chemical ranges

### First type

A claimed range is novel if it is outside the prior-art range. The endpoint of a prior-art range is considered a specific disclosure, with the same quality as an example value disclosed with the prior-art range.

The case below describes a claimed range (blue) and a prior-art range (red). The ranges do not overlap:



For disclosed values, such as endpoints or from examples, scientific rounding rules apply (unless the description specifies otherwise).

### Examples

Prior-art disclosure "X" discloses a value of 4.7%, which anticipates the claimed range 5-50% because when "4.7" is rounded to the same precision as the disclosed endpoint value "5", the disclosure in fact is equivalent to "5".

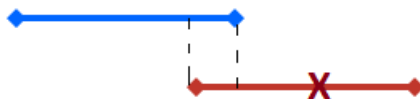


**Legal references:**  
Art. 54 EPC, GL G-VII, 8, T 175/97, CL Book I.C.6.3, I.C.6.3.2

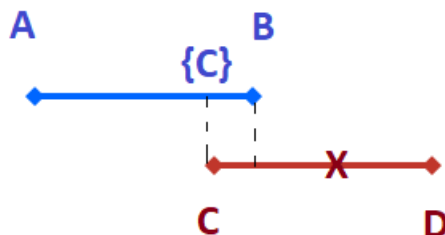
### Second type

A claimed range is not novel if it overlaps with a prior-art range. Prior-art endpoints of a range and individual examples in the overlapping area take away novelty. The endpoint of a prior-art range is considered a specific disclosure, with the same quality as an example value disclosed with a prior-art range.

In the case below, the lower endpoint of the prior-art range (red) takes away the novelty of the claimed range (blue). Even though there are no actual examples "X" in the area of overlap, the endpoint is sufficient to take away novelty.



However, disclaiming the endpoint "C" of the overlapping range may be insufficient to re-establish novelty even if no other values (like "X") are disclosed in the overlapping range.



Thus, a claim to "with a value ranging from A-B, without value C" might not be novel:

- a. What has the prior art actually made available to the public (by way of examples and also general teaching) and can the skilled person use this teaching to work "close to endpoint C"? (T.666/89, Guidelines G-VI, 7)
- b. Would the skilled person **seriously contemplate** working there? (T.26/85)

### Examples

A shampoo claims a composition with two ranges:

- a. 8-25% anionic surfactant and
- b. 0.001-0.1% cationic polymer

A prior-art shampoo discloses a composition where the ranges are:

- a. 5-25% anionic surfactant and
- b. 0.1-5.0% cationic polymer

The claimed composition is considered not novel (T.666/89).

### Legal references:

Art. 54 EPC, GL G-VII, 8(iii), CL Book I.C.6.3.2, T 666/89, T 26/85

### Third type

A claimed sub-range falling within a broader disclosed range is a selection invention and can be novel if:

- a. the selected sub-range is *narrow* vis-à-vis the prior-art range
- b. the selected sub-range is *sufficiently far removed* from any specific examples and the endpoints of the known range.



The interpretation of the terms "narrow" and "sufficiently far removed" depends on the technical situation and needs assessing on a case-by-case basis.

The Guidelines have been revised in relation to the criteria for the novelty of sub-ranges. Older case law also considered a third point relevant for sub-range novelty, namely that the sub-range was not arbitrarily chosen but resulted from a "purposive selection". This meant that there should be a "technical effect" associated with choosing this sub-set. Now, though, this aspect is dealt with under inventive step (Article 56 EPC), not novelty (Article 54 EPC).

### Examples

The claim of an application relates to a ratio range of  $\text{SiO}_2/\text{Al}_2\text{O}_3$  from 2-12.

The prior art discloses a ratio  $\text{SiO}_2/\text{Al}_2\text{O}_3 > 1$ .

Claim 1 of application: silica & alumina in ratio of 2-12
--------------------------------------------------------------

Prior art: silica & alumina in ratio $> 1$
-----------------------------------------------

The prior-art ratio is an "open range" (i.e. it has no upper limit).

The claimed range is novel over the prior-art range as:

- The disclosed endpoint "1" does not fall into the claimed sub-range.
- In view of the "open range" claim (" $> 1$ "), the claimed range "2-12" may be said to be "narrow".

A case-by-case analysis is required if, in the technical field in question, the lower endpoint of the claimed range (i.e. "2") is sufficiently far removed from the prior-art examples/endpoint (i.e. from "1").

In T.0230/07, this was considered to be the case and the sub-range was considered novel.

### Legal references:

Art. 54 EPC, GL G-VII, 8(ii), CL Book I.C.6.3.1, T 261/15, T 279/89

## 8. Products by process

Product-by-process claims are those that have the scope of protecting a product whereby the product is defined by how it is produced. They are in the format: "Product X obtained through the process of [steps]".

The words "obtained", "obtainable", "directly obtained", etc. are indicative of a product-by-process claim.

Thus, a product-by-process claim defines the entity by way of a production process and must be construed as a claim to the product as such. Therefore, novelty must be compared with any prior art mentioning the product.

A preparation method can confer novelty on a product if the process imparts characteristic features on the final product that distinguish it over prior-art products.

A new process does not necessarily render the product-by-process claim novel. What matter are the technical properties imparted on the product by the process.

A requirement for this claim category is that it must be *impossible to define* the claimed *product any other way* than through the process and that the **entity as such is new and inventive** because the process has provided the product with technical features/properties that distinguish the product from any prior-art material.

An example of a product-by-process claim is "carbon black" made from acetylene combustion. An alternative expression for "carbon black" is soot. "Carbon black" made from acetylene combustion can be physically distinguished from "carbon black" made from e.g. birch tar combustion. The material cannot be properly defined (in terms of chemical structure) or better defined other than through the process since this imparts distinguishable properties on the product. For instance, "carbon black made from acetylene combustion" has higher conductivity and crystallinity than "carbon black made from birch tar".

### Examples

What is claimed is:

"A tablet obtained by melt-extruding a powder blend of nifedipine and PVP."

Prior art:

"A tablet of nifedipine and PVP obtained by wet-granulation."

The tablets have different dissolution rates and different stability of the active ingredient nifedipine in the medicament.

### Legal references:

Art. 54 EPC, GL F-IV, 4.12, CL Book II.A.7.6

## 9. Enabling disclosure – hits in databases

Under Article 54(2) EPC, the state of the art is everything *made available to the public* by means of a written or oral description, by use, or in any other way, before the date of filing of the European patent application.

Therefore, a chemical compound whose name or formula is stated in a prior document is not to be considered known (i.e. prior art) unless **information is provided that enables the compound to be prepared**. For a naturally occurring compound, this may entail that means for isolating it are provided or described because only then has it been "*made available to the public*".

Consequently, when the search for the novelty of a Markush formula provides a hit "Y" in database X but database X does not link "Y" to any bibliographic data or report any physical values for "Y", then "Y" is/might not be considered an "*enabling disclosure*" because "Y" has not really been made "*available to the public*".

In the **absence** of proper information, the following questions are relevant when judging if the disclosure is enabling:

- Is the substance reported with a melting point (indicator that substance actually existed)?
- How difficult is it to synthesise the compound (routine or trial-and-error situation of bench chemistry)?

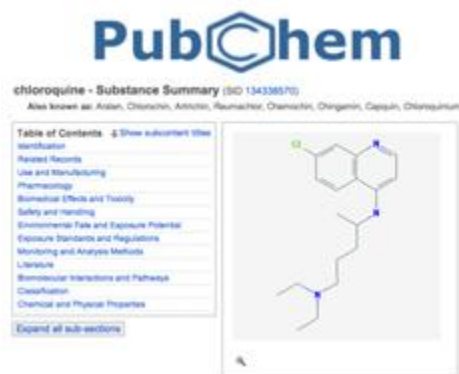
## Examples

A **prior-art document** discloses a chemical compound "Y" (identified by name or by structural formula), indicating that the compound may be produced by a process defined in the document itself.

The document, however, **does not indicate how to obtain the starting materials and/or reagents** used in the process of making "Y". The skilled person in this particular case cannot obtain these starting materials or reagents on the basis of common general knowledge (e.g. from textbooks). As a consequence, there is insufficient disclosure in the prior-art document on how to make "Y".

Because there is insufficient information on how to make "Y", this compound is not disclosed in an enabling way and the prior-art document is not prejudicial state of the art as per Article 54(2) EPC.

The Pubchem database contains many compounds that have never been made but rather were computer-generated and their physico-chemical properties calculated. Entries such as these mostly have no link to any publication with teaching on how to make these compounds, so they are not disclosed in an enabling way.



## Legal references:

Art. 54 EPC, GL G-IV, 2, CL Book II.A.7.6

## 10. Enabling disclosure – undisclosed synthesis

Under Article 54(2) EPC, the state of the art is everything **made available to the public** by means of a written or oral description, by use, or in any other way, before the date of filing of the European patent application.

A chemical compound/composition is considered not "**made available to the public**" if it is the product of a reaction cascade and where either the starting material or intermediates are not known and their synthesis is not disclosed.

A prior-art disclosure with a chemical compound/composition not "**made available to the public**" is not novelty-destroying.

## Examples

A claim relates to substance D.

The prior art discloses a process for making compound D from the following sequence:

**A + B -> C -> D**

(A + B react to give C, which is then further converted to final product D.)

Starting materials A and B are not commercially available and their synthesis is not disclosed.

The synthesis of C and D is fully disclosed.

The claim to substance D is novel over the prior-art disclosure of D because the prior art has not disclosed D in an enabling way (T 206/83, OJ 1987, 5).

### Legal references:

Art. 54 EPC, T 206/83, OJ 1987, 5

## 11. First medical use – claim format

A claim in the form "Use of substance or composition X for treating disease Y ..." will be regarded as relating to a method for treatment explicitly excluded from patentability under Article 53(c) EPC and therefore will not be accepted.

A claim in the form "Substance X for use as a medicament" is acceptable even if X is a known substance, provided that its use in medicine is not known. Accordingly, the claim category must be a product/entity claim with a purpose limitation (the medical use, "for use") and not a use or method claim category.

For example:

- "Use of substance X in treating asthma" is excepted from patentability under Article 53(c) EPC, but a claim reading "Substance X for use in treating asthma" is allowable under Article 54(4) and (5) EPC.
- "Substance X for treating asthma" is interpreted as "suitable for"; the wording "for use" is essential for protection under Article 54(4) and (5) EPC.
- "Substance X for use in cosmetics" is also interpreted as "suitable for" because cosmetic treatment is not excepted from patentability under Article 53(c) EPC. Accordingly, a claim reading "Use of substance X in cosmetic treatment" is acceptable and does not require the "special" medical-use wording under Article 54(4) and (5) EPC.

To know what can be claimed for a further medical use under Article 54(4) and (5) EPC, it is of paramount importance to distinguish between substances/compositions as per Article 54(4) and (5) EPC and other products, such as devices, which are not considered substances/compositions. A claim directed to a device for an intended medical use (e.g. pacemaker or implantable chemical sensor for use in ...) must be construed as claiming a device which is suitable for that medical use (Guidelines F-IV, 4.13). Substances or compositions may be claimed as such or as a particular dosage form (solutions, granulates, dispersions, aerosols, etc.).

## Legal references:

Art. 53(c) EPC, Art. 54(4) EPC, GL G-VI, 6.1, T 1099/09, T 1069/11, T 1578/15

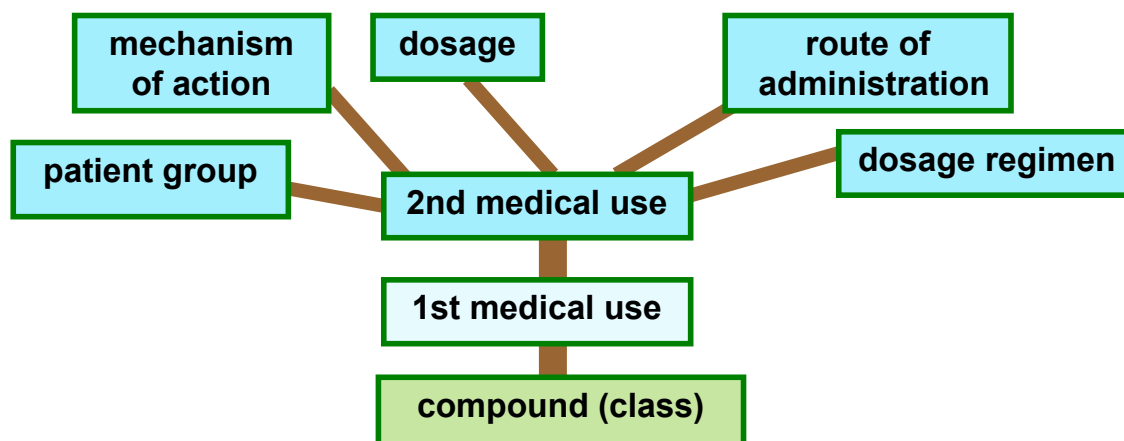
## 12. Second medical use – claim format

For the first medical use, a claim in the form "Substance X for use as a medicament" is acceptable even if X is a known substance, provided that its use in medicine is not known. Likewise, for the second or further medical use, it is acceptable to have a claim in the form "Substance X for use in treating disease Y" provided that any such claim involves an inventive step over any prior art disclosing the use of X as a medicament.

Article 54(5) EPC reads: "... 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) EPC, provided that such use is not comprised in the state of the art." Accordingly, in addition to the requirements for the first medical use (product claim, substance/composition), the medical use must be "specific" (or rather, more specific) with regard to the first medical use. Novelty can be derived from a different disease, mode of application, patient group, dosage regimen, etc.

Thus, therapeutic uses of a substance/composition may be based not only on treating a different disease but also on treating the same disease by a different therapeutic method that differs, for example, on account of the dosage, administration regimen, group of subjects or route of administration (Guidelines G-VI, 6.1.2, G 2/08).

Furthermore, the claim must specify the medical indication, i.e. the disease (T 241/95, T 830/08). If the further therapeutic use relates to a different therapy for the same disease using the same substance/composition, the claim must also specify all the technical features of the therapy giving rise to the desired technical effect (Guidelines GL G-VI, 6.1.2, G 2/08).



### New therapeutic applications can be based on

1. a different disease
2. a new group of patients (T19/86, T233/96)
3. a different mode of drug administration (T51/93)
4. a different dosage regimen (T56/97, T317/95, G2/08)
5. a new clinical situation (T29/86, T406/06)

An independent claim directed to a **further therapeutic use** of a substance/composition based on using said product in treating a **different disease** must be formulated as follows:

Substance X or Composition comprising X	for use	in a method for the treatment of Y, or in the therapy of Y, or in a method of treating Y, or in a method of therapy of Y, or as a medicament defined by its function, (e.g. as an anti-inflammatory medicament)
--------------------------------------------------	---------	-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

If the further therapeutic use is based on using the same product in a **different treatment** of the **same disease**, the independent claim must be formulated as follows:

Substance X for use or Composition comprising X for use	in a method for the treatment of Y, or in the therapy of Y, or in a method of treating Y, or in a method of therapy of Y, or as a medicament defined by its function (e.g. as an anti-inflammatory medicament)	characterised in that/ wherein	other features (e.g. the substance/ composition is administered topically, three times daily...)
------------------------------------------------------------------------	----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	-----------------------------------	--------------------------------------------------------------------------------------------------------------

#### Legal references:

Art. 54(5) EPC, GL G-VI, 6.1.1, GL G-VI, 6.1.2, G 2/08, T 241/95, T 830/08

### 13. Second medical use – claim format for dependent claims

The wording of the dependent claims must clearly reflect their dependency on the independent claim. A suitable formulation may read:

Substance (X) or Composition (comprising X) (according to claim #)	for use in the therapy of disease Y according to claim # or for use according to claim #	wherein	other features (e.g. it is provided as water- soluble granulates)
-----------------------------------------------------------------------------	---------------------------------------------------------------------------------------------------	---------	-------------------------------------------------------------------------

Claims depending on a medical use claim **must contain** the wording "**for use** according to claim 1" because medical use claims are purpose-limited product claims. Without this purpose-limitation wording, it might be considered that the dependent claim referred to the product per se and the medical use of the dependent claim would not be considered for novelty (Articles 84 and 54 EPC).

In the following example, the dependent claim is **not** correctly formulated under Article 54(5) EPC:

Claim 1: Composition comprising X for use in treating Y.

Claim 2: Composition according to claim 1, comprising 5 mg X.

The category of claim 2 is unclear and the dependency doubtful. The claim appears to depend on a claim directed to a product per se. The claim would also lack novelty over any prior art disclosing a composition comprising 5 mg X, or a first medical use of it. Claim 2 has to be worded as "Composition **for use** according to claim 1, comprising 5 mg X" in order to clearly reflect the Article 54(5) EPC format.

#### Legal references:

Art. 84 EPC, Art. 54(5) EPC, GL G-VI, 6.1.5

## 14. Swiss-type claims

Although obsolete, this claim format helps understand the development of medical use claims.

In an application with a priority date **after 28 January 2011**, only the Article 54(5) EPC format is allowable; for "Swiss-type claims", the medical use is **no longer considered** to establish novelty (G 2/08).

Under the EPC 1973, a patent for a further medical use could, pursuant to a line of case law first set out in decision G 5/83, be granted for a claim directed to "the use of a substance or composition for the manufacture of a medicament for a specified therapeutic application" (a Swiss-type claim). The novelty of the subject-matter of this kind of claim could be derived not only from the novelty of the substance or of the method of manufacture, but also from the new therapeutic application (G 5/83). This "special approach to the derivation of novelty" constituted a narrow exception to the general novelty requirement and was not to be applied in other fields of technology.

With the EPC 2000, former Article 54(5) EPC 1973 ("first use in a medical method") was renumbered Article 54(4) EPC and a new Article 54(5) EPC was introduced to provide protection for second medical uses. The new Article 54(5) EPC eliminates any legal uncertainty on the patentability of further medical uses. It unambiguously permits purpose-related product protection for each further new medical use of a substance or composition already known as a medicine.

Swiss-type claims are so named as they were originally approved by the Swiss Patent Office as a mechanism to enable protection for a new therapeutic use of a known compound (i.e. a second or further medical use), given that claims to methods of medical treatment were prohibited.

A claim in the Swiss-type format is a purpose-related **process** claim, whereas a claim drafted in accordance with Article 54(5) EPC is a purpose-related **product** claim. Therefore, these claims have different categories, with the following consequences:

- If a parent application has been granted with a Swiss-type claim, granting a patent on the basis of the purpose-related product claim in its divisional application would not lead to double patenting (T 13/14; see also Guidelines G-IV, 5.4).
- Since a claim to a particular physical activity (e.g. method, process, use) confers less protection than a claim to the physical entity per se (G 2/88, Reasons 5.1), a Swiss-type claim offers less protection than a claim formulated according to Article 54(5) EPC. Therefore, a change from a Swiss-type claim to a claim drafted in accordance with Article 54(5) EPC contravenes Article 123(3) EPC (T 1673/11; see also Guidelines H-IV, 3.4).

#### Legal references:

Art. 54(5) EPC, G 2/08, G 5/83

## 15. Non-allowable medical claim formats

Certain medical claim formats may be "allowable" but do not have the purpose limitation under Article 54(4) and (5) EPC.

The following examples do not fall under the limitations of Article 54(4) and (5) EPC:

Substance X **for treating asthma**

⚠ not the "for use" wording

Substance X **for use in cosmetic treatment/in an *in vitro* method**

⚠ not methods excepted from patentability under Article 53(c) EPC

Substance X **for use as an antifungal/antibacterial agent/in topical treatment**

⚠ the claims do not define a specific medical use of the claimed product. They encompass non-medical uses because antifungal/antibacterial agents or topical treatments are also used in e.g. agriculture for treating plants (Guidelines G-VI, 6.1.2).

**Legal references:**

Art. 54(4) EPC, Art. 54(5) EPC, Art. 53(c) EPC, GL G-VI, 6.1.2

## **16. Diagnostic and surgical uses pursuant to Article 54(5) EPC**

Article 53(c) EPC is based on socio-ethical and public health considerations. Medical and veterinary activities should not be restrained by patent rights, i.e. medical doctors should not be hindered from exercising their professional skills when helping their patients (G 5/83, G 1/04, G 1/07).

Article 53(c) EPC reads: "European patents shall not be granted in respect of methods for treatment of the human or animal body by **surgery** or **therapy** and **diagnostic** methods practised on the human or animal body ..."

A single surgical or therapeutic step in a multi-step method (even if only implicit) is sufficient to exclude the whole claim from patentability (G 1/07, G 1/04).

However, methods for merely obtaining information from the living body such as X-ray investigations are not considered surgical or therapeutic steps and are therefore not excluded from patentability under Article 53(c) EPC.

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 all the necessary phases are included in the claim (Guidelines G-II, 4.2.1.3, G 1/04).

Methods of collecting data *in vivo* (including imaging, measuring physiological parameters, staining *in vivo*) for merely obtaining ("collecting" as used in G 1/04) information (data, physical quantities) from the living human or animal body and methods for measuring physiological parameters on the human/animal body (e.g. X-ray investigations, MRI studies, MRI/PET/X-ray/CT/ultrasound imaging and blood pressure measurements) are not excluded from patentability under Article 53(c) EPC.

The following claims relating to these methods are possible (Guidelines [G-VI, 6.1.3](#)):

- Substance or composition X for use as a contrast agent for imaging blood flow. (Read as "suitable for", so novelty must be derived from the product itself and not from the use; Guidelines [F-IV, 4.13.1](#).)
- Use of substance X (as a contrast agent) for imaging blood flow.
- A method of imaging blood flow using substance X.

A **diagnostic** claim under [Article 54\(5\) EPC](#) may read:

"Substance X for use in a method **of *in vivo* diagnosis** of disease Y."

The wording "*in vivo*" limits the scope of the claim to diagnostic methods, which are excluded from patentability pursuant to [Article 53\(c\) EPC](#). Accordingly, the above-mentioned example is a purpose-limited product claim as per [Article 54\(5\) EPC](#).

The terms "*in vitro*" or "*ex vivo*" do **not** define a diagnostic use within the meaning of [Article 53\(c\) EPC](#) and can thus be formulated as use or method claims.

As set out above, a claim reading "Substance X for use as a contrast agent for imaging blood flow" does **not** define a diagnostic use under [Article 53\(c\) EPC](#) because it is merely a method of obtaining information from the body.

Purpose-related product claims which do **not** define a diagnostic use excluded from patentability under [Article 53\(c\) EPC](#) are construed as claims directed to a product per se which is suitable for the claimed use.

The participation of a medical or veterinary practitioner, through being present or bearing the responsibility, is not decisive for determining whether or not a method is a diagnostic method. It is also irrelevant whether all the method steps could also – or only – be practised by medical or non-medical support staff, the patient themselves or an automated system (see also [G 1/07](#)).

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 Guidelines [G-II, 4.2.1.1](#) and [G 1/07](#).

**Surgical methods** excluded from [Article 53\(c\) EPC](#) 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.

In contrast, 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.

Methods of collecting data *in vivo* or imaging (i.e. diagnosis) may include a surgical step that has to be objected to under [Article 53\(c\) EPC](#), but they may be claimed as a purpose-limited product claim under [Article 54\(5\) EPC](#).

#### **Legal references:**

Art. 53(c) EPC, Art. 54(5) EPC, GL G-VI, 6.1, GL G-VI, 6.1.4, G 1/07, G 1/04, CL Book I.B.4.5.1

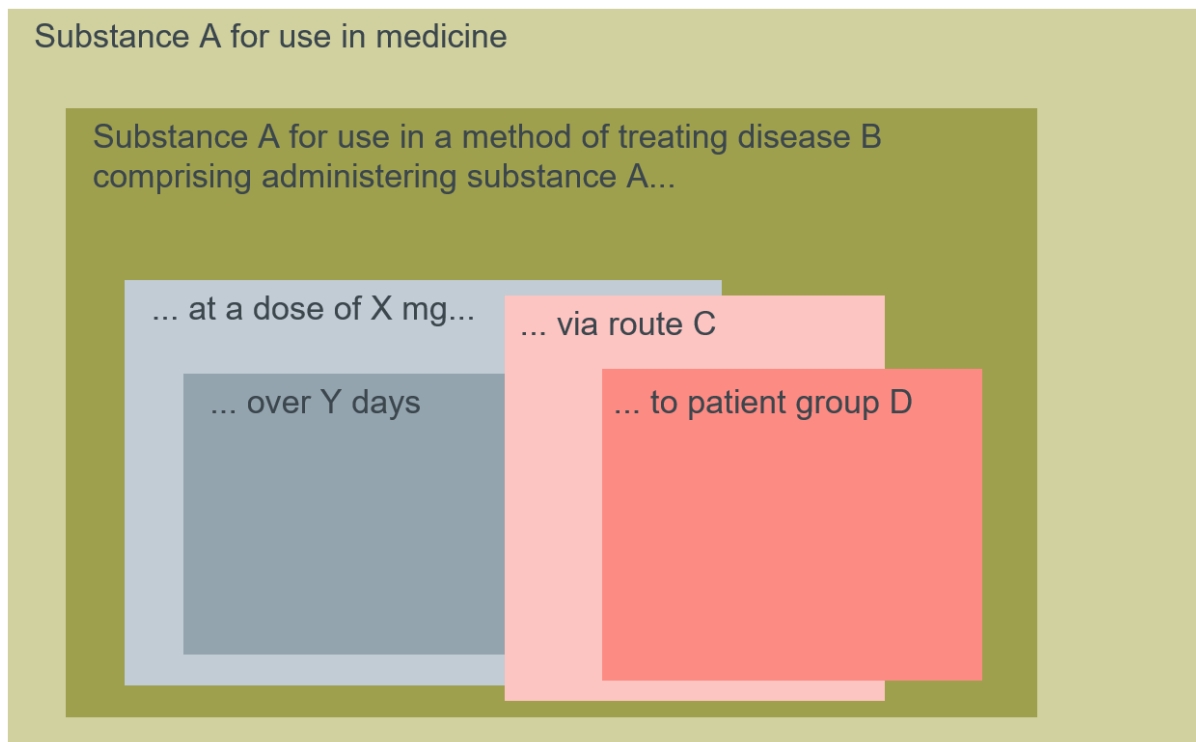
## 17. Characterising features in second medical use claims: groups of patients

Second or further medical use claims make it possible to protect "any specific use" in a method of therapy, diagnosis *in vivo* or surgery as long as that use is not part of the prior art.

G.2/08 does not provide a limitation to the "use" other than it has to be specific and fall under the scope of Article 53(c) EPC:

The "specific use" is not limited to a new disease. Rather, it can refer to a different technical feature related to the therapeutic indication, like a new group of patients, mode or route of administration, clinical situation or dosage regimen.

When claims attempt to actively define a patient group (or sub-group) by incorporating a method of identifying that sub-group, it has to be clearly derivable from the claim which sub-group is actually selected and that this is the sub-group for which a therapeutic effect has been established. If this is not the case, there may be a lack of clarity and inventive step.



According to the established case law of the boards of appeal, the use of the same compound in the treatment of the same disease for a particular group of subjects can nevertheless constitute a novel therapeutic application, provided that it is carried out on a new group of subjects which is **distinguished** from the former by its **physiological or pathological status** (Case Law Book I.C.7.2.4).

The new feature must provide a technical teaching that is different from the teachings in the prior art.

An example of distinguishable patient groups as per Article 54(5) EPC is **T 734/12**. Patient groups **may overlap** as long as they can be distinguished. The claim relates to rituximab for treating rheumatoid arthritis (RA) in a human who experiences an inadequate response to TNF  $\alpha$ -inhibitors;

the prior art discloses rituximab for treating RA in humans with inadequate response to MTX (an antimetabolite).



The claimed group of patients overlaps with those in the prior art but they can be distinguished on account of their physiological/pathological status. Therefore, this is novel under Article 54(5) EPC.

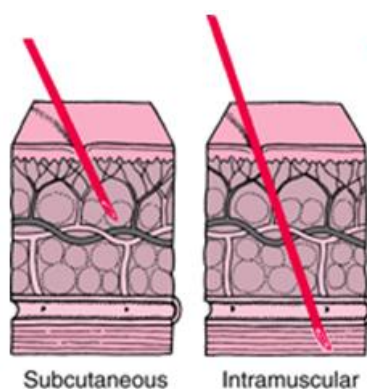
#### Legal references:

Art. 53(c) EPC, Art. 54(5) EPC, CL Book I.C.7.2.4, T 734/12

## 18. Characterising features in second medical use claims: route of administration

In T 51/93 the only difference between the invention as claimed and the disclosure of D(4) was that the claim was directed to an intended method of **subcutaneous administration**. The board stated that a different mode of administration for a pharmaceutical could impart novelty on a medical use claim drafted in accordance with decision G 5/83. Patentability was to be treated as depending only on whether this modification was in fact novel and inventive.

Example: "Substance X for use in treating disease Y by subcutaneous administration"



#### Legal references:

Art. 53(c) EPC, Art. 54(5) EPC, CL Book I.C.7.2.4

## 19. Substance or composition as per Article 54(4) and (5) EPC

Purpose-limited product claims under Article 54(4) and (5) EPC are limited to a **substance or composition** in the context of its medical use which imparts novelty and non-obviousness, if any, on the claimed product. Accordingly, **a device is not intended** to enjoy the purpose limitations under Article 54(4) and (5) EPC.

Although neither the European Patent Convention nor the Guidelines for Examination give an explicit definition of substance, composition or medical devices, the Guidelines (G-VI, 6.1.1) do refer to T.1758/15 for further guidance on products that can be deemed "substances or compositions" as per Article 54(4) and (5) EPC.

The Guidelines also state that this protection cannot be extended to products other than "substances or compositions". A claim directed to a device for a medical use must be construed as claiming a device which is "suitable for" that medical use (Guidelines F-IV, 4.13).

It is clear from T.1758/15 that "substance or composition" is not restricted to medicaments. It is also generally accepted that cells, diagnostic agents and prophylactics can benefit from Article 54(4) and (5) EPC, as can kits, scaffolds or matrices comprising these substances or compositions.

It is important to note that in T.1758/15 it is pointed out that Article 54(4) and (5) EPC refers not only to therapeutic and diagnostic methods, but also to methods of surgery. It is concluded that the same principle should apply to all. In other words, the "substance or composition" does not need to have a therapeutic effect for surgical and diagnostic methods but it should actively contribute to achieving the effect of the claimed medical method.

A product qualifies as a "substance or composition" under Article 54(4) and (5) EPC if it is the active agent or ingredient in the specific medical use and if the therapeutic effect can be ascribed to its **chemical properties** (see G.5/83 and T.1758/15).

For example, consider a filler material which is injected between a first tissue targeted for radiation treatment and a second sensitive tissue which is to be protected from radiation. If the shielding effect of the filler material is achieved by a **mere mechanical displacement** of the sensitive tissue relative to the target tissue, due to the volume it occupies between the two tissues, the filler material **qualifies as a device** rather than a substance or composition. On the other hand, if the filler material provides a radiation-reducing effect for the sensitive tissue that could be **attributed to its chemical properties**, it would be considered a **"substance or composition"** as per Article 54(5) EPC.

Another example is a fibrin glue formulation comprising components selected from fibrinogen, an enzyme (such as thrombin) which can form fibrin when it reacts with fibrinogen, a catalyst capable of inducing cross-linking of fibrin, and a visualisation agent for use in preventing or treating surgical adhesions. Protection under Article 54(4) and (5) EPC can be allowed because **the therapeutic effect**, in this case preventing surgical adhesions, is achieved by a fibrin clot. Fibrin clot formation is based on an enzymatic reaction which interacts with the coagulation cascade in the body, so it is **directly attributable to the material** from which the product in question is made.

#### Legal references:

Art. 54(4) EPC, Art. 54(5) EPC, GL G-VI, 6.1.1, T 1758/15

## 20. Difference between substance/composition under Article 54(4) and (5) EPC and a medical device

Article 54(4) and (5) EPC acknowledges the notional novelty of substances or compositions even when they are already as such part of the state of the art, provided the new use is one excluded from patent protection under Article 53(c) EPC. Put another way, even if a chemical

compound/composition is known, a claim to that chemical compound/composition for use in therapy is novel if no medical use of the chemical compound/composition has been described before.

In chemistry, a substance can be defined as any material with a specific chemical composition.

A composition can be defined as the combination of distinct parts or elements to form a whole: a mixture of elements.

Argon, iron, water and aspirin are examples of "*substances*" as per Article 54(4) and (5) EPC – they are **specific** chemical entities.

Alloys or polymer blends are examples of "*compositions*" – they are a mixture of parts or elements to form a whole.



Products of the pharmaceutical industry generally referred to as "drugs" are "substances".

Products of the pharmaceutical industry such as tablets or ointments are generally referred to as "compositions".

A medical apparatus may be composed of several materials, but the apparatus as a whole is neither generally nor necessarily considered a "composition". Every device is ultimately made from chemical substances or compositions (which influence the device's characteristics and thus determine at least some of the effects the device has or does not have on the body). If **any** material from which a device is made was considered a "**substance or composition**" as per Article 54(5) EPC, this would negate the distinction between products which are "substances or compositions" and those which are not. A narrower interpretation of substance or composition under Article 54(5) EPC is therefore required (T.1758/15, Reasons 5.2.3 and 5.2.4).

It is clear from T.1758/15 that "substance or composition" is not restricted to medicaments. It is also generally accepted that cells, diagnostic agents and prophylactics can benefit from Article 54(5) EPC, as can kits, scaffolds and matrices comprising these substances or compositions (T.1758/15).

It is important to note that in T.1758/15 it is pointed out that Article 54(4) and (5) EPC refers not only to therapeutic and diagnostic methods, but also to methods of surgery. It is concluded that the same principle should apply to all. In other words, the "substance or composition" does not need to have a therapeutic effect for surgical and diagnostic methods but it should actively contribute to achieving the effect of the claimed medical method.

## Examples

An application related to a "column" filled with a polymer, used to remove immunoglobulins from the plasma of patients suffering from dilated cardiomyopathy. The polymeric material of the column bound to the immunoglobulins. The polymeric material was considered a "composition".

The column holding the polymeric material was only a carrier – it was not instrumental in achieving any therapeutic effect and not a "substance" or "composition" within the meaning of decision G 5/83 (T.2003/08).

### Legal references:

Art. 54(4), (5) EPC, CL Book I.C.7.2.4 g), G 5/83

Distinguishing between a medical device (to which Article 54(4) and (5) EPC would not apply; the use is not a limiting factor) and substances/compositions (to which Article 54(4) and (5) EPC applies) is not easy as many medical devices (such as stents or a bone cement) are clearly made of a mixture of materials and are therefore chemical compositions in the sense of the word.

To determine whether they are then also "compositions" under Article 54(4) and (5) EPC, their role in the body has to be assessed. If substances or compositions such as these are consumed and metabolised, they qualify for the exception under Article 54(4) and (5) EPC, i.e. the use becomes a limiting feature.

When these "compositions" achieve their effect through a physical interaction with the body, they do not qualify for the exception in Article 54(4) and (5) EPC.

The following decision path leads to the correct assessment:

a. Is the entity for use describing a method falling under Article 53(c) EPC?

If yes à (b)

b. Is the entity a compound or composition under Article 54(4) and (5) EPC?

If yes à (c)

c. Is the claimed entity's main intended function a physical one?

If yes à Article 54(4) and (5) EPC does not apply

If no à (d)

d. Is the claimed entity's main intended function a biochemical one? Is the entity consumed/metabolised?

If yes à Article 54(4) and (5) EPC applies

## Examples

A stent (made out of a mixture of polymers) is not a "composition" as per Article 54(4) and (5) EPC because it achieves the therapeutic effect (vasodilation) through physical means and is not metabolised or consumed.

A bone cement is a chemical mixture but not a "composition" as per Article 54(4) and (5) EPC because it achieves the therapeutic effect (fixation of implants) through physical means and is not metabolised.

A liquid nutrient composition is claimed for promoting gut health in elderly patients. The nutrient composition is a "composition" as per Article 54(4) and (5) EPC because it achieves its effects through biochemical means (gut flora stimulation) and is consumed.

**Legal references:**

Art. 54(4) EPC, Art. 54(5) EPC, CL Book I.C.7.2.4 g), G 5/83

## **21. Beyond the course**

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

<https://www.ema.europa.eu/en/human-regulatory/overview/medical-devices>

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