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Learning path for patent examiners

Patentability: exceptions and exclusions: Advanced level

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Introduction

This publication, "Patentability: exceptions and exclusions, Advanced 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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All references to natural persons are to be understood as applying to all genders.

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1. Learning objectives

Participants to this course will learn:

- The importance of balancing animal suffering and medical benefit for inventions in biotechnology.
- The definition and the legal basis of patents on microbiological processes.
- The patentability requirements for inventions related to biological sequences.
- The differences between cosmetics and medical use claims.
- Some examples of patentable and non-patentable subject-matter related to the human body and its parts

2. Animal suffering without substantial medical benefit

Under the exceptions to patentability, Article 53(a) EPC reads:

"European patents shall not be granted in respect of inventions the commercial exploitation of which would be contrary to 'ordre public' or morality; such exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States."

This is developed further under Rule 28(1)(d) EPC:

"Under Article 53(a), European patents shall not be granted in respect of biotechnological inventions which, in particular, concern the following:

processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes."

To assess Rule 28(1)(d) EPC, a test was developed in T 315/03 (oncomouse, Harvard University) for the consideration of animal suffering, medical benefit and the necessary correspondence between the two in terms of the animals in question.

According to the board, the test was to be applied to ensure that a patent was extended only to those animals whose suffering was balanced by a medical benefit.

This balancing test requires three matters to be evaluated, namely:

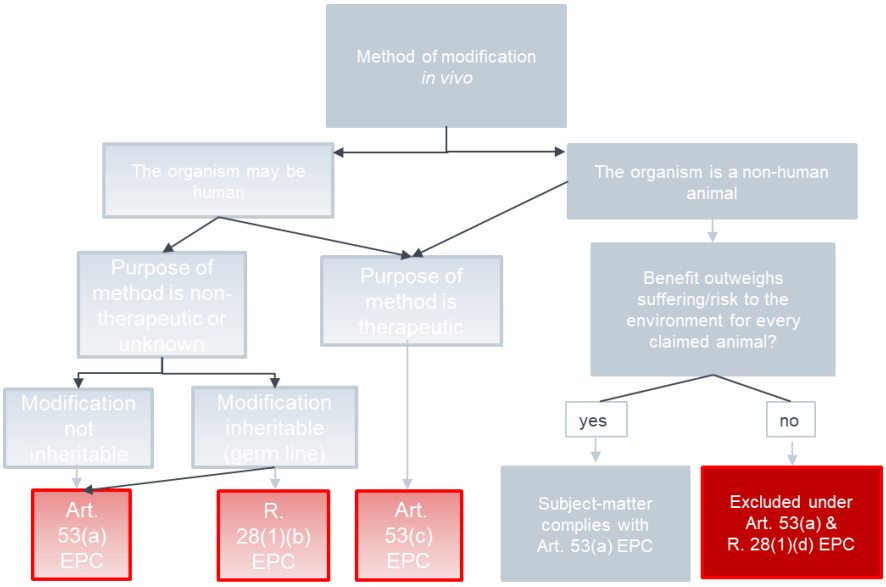
- whether animal suffering is likely
- whether likely substantial medical benefit has been established
- whether the suffering and the medical benefit both exist in relation to the use of the same animals

In the board's view, the first two followed axiomatically from the wording of Rule 28(1)(d) EPC. The third matter had to follow too; otherwise the rule could be circumvented.

To take a hypothetical example, if likely suffering to both cats and lions was established, it would nonetheless be contrary to Rule 28(1)(d) EPC to allow claims which encompassed both cats and lions when the only established likely medical benefit arose in relation to the use of cats.

In short, Rule 28(1)(d) EPC should be applied to ensure that patents only extended to those animals whose suffering was balanced by a medical benefit. This is what is meant by the necessary correspondence between suffering and benefit.

The test can be performed as follows:



Examples

Method for technically modifying an animal:

A method for producing a non-human animal model for heart failure comprising
(a) the administration of the lncRNA as defined in claim 1 to the myocardium of the animal, and
(b) the induction of pressure overload in the myocardium of the animal.

The claim concerns the use of long non-coding RNAs (used as transcription regulators) in producing an animal model for heart failure.

The test would be performed as follows:

1. The animal is non-transgenic, so the balancing test is carried out under Article 53(a) and not under Rule 28(1)(d) EPC.
2. The animal model is for cardiomyopathy, so suffering is undeniable.
3. Does the benefit to humankind (e.g. medical benefit) outweigh the suffering for every claimed animal?
4. According to the description, the animal may be swine, monkeys, rats or mice.
5. Mice are used in the examples, so there is experimental evidence of the benefit of the animal model for mice. The benefit can be extrapolated to similar lab models such as rats (although this is not validated practice).
6. However, the applicant has to show that the use of swine or monkeys would lead to results which would not be achievable with mice or rats. The argument that monkeys or pigs are closer models to human beings cannot be taken into account.
7. The application does not indicate why larger animals would be needed – no evidence of the benefit – so the claim is excluded under Article 53(a) EPC.

Legal references:
Art. 53(a) EPC, R. 28(1)(d) EPC, T 315/03

3. Definition of microbiological process

Microbiological processes and their products are explicitly mentioned as being patentable subject-matter in the following:

- Article 53(b) EPC:
  "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 27(c) EPC:

"Biotechnological inventions shall also be patentable if they concern a **microbiological or other technical process** or a product obtained by means of such a process other than a plant or animal variety."

"Microbiological process" means any process involving or performed upon or resulting in microbiological material. Hence, the term "microbiological process" is to be interpreted as covering not only processes performed upon microbiological material or resulting in that material, e.g. by genetic engineering, but also processes which, as claimed, include both microbiological and non-microbiological steps.

Rule 27(c) EPC:

- The product of a microbiological process may also be patentable per se (product claim). Propagation of the micro-organism itself is to be construed as a microbiological process for the purposes of Article 53(b) EPC.
- Consequently, the micro-organism can be protected per se as it is a product obtained by a microbiological process (see Guidelines G-II, 3.1). The term "micro-organism" includes bacteria and other generally unicellular organisms with dimensions beneath the limits of vision which can be propagated and manipulated in a laboratory (see T 356/93), including plasmids, viruses and unicellular fungi (including yeasts), algae, protozoa and human, animal and plant cells. Isolated plant or animal cells or *in vitro* plant or animal cell cultures are treated as micro-organisms since cells are comparable with unicellular organisms (G 1/98, 5.2).

  On the other hand, product claims for plant or animal varieties cannot be allowed even if the variety is produced by means of a microbiological process (Rule 27(c) EPC). The exception to patentability in Article 53(b) EPC, first half-sentence, applies to plant varieties irrespective of the way in which they are produced.

  However, plant cells or tissues are usually totipotent and are able to regenerate the full plant. Therefore, even if plant cells or cell cultures may be regarded as the product of a microbiological process, plant material which is able to propagate the full plant is excluded from patentability if the plant from which the material originates has been exclusively produced by an essentially biological process (G 3/19).
- T 356/93:
  Point 34: "… the term 'microorganism' includes not only bacteria and yeasts, but also fungi, algae, protozoa and human, animal and plant cells, i.e. all generally unicellular organisms with dimensions beneath the limits of vision which can be propagated and manipulated in a laboratory. Plasmids and viruses are also considered to fall under this definition" (Guidelines G-II, 5.5.1).

Legal references:
Art. 53(b) EPC, R. 26(6) EPC; R. 27(c) EPC, GL G-II, 5.5.1, G 1/98, 5.2, CL Book I

4. Non-patentable biotechnological inventions, advanced

Rule 28 EPC lists a number of non-patentable biotechnological inventions as follows:

Rule 28(1) EPC:

Under Article 53(a) EPC, European patents will not be granted in respect of biotechnological inventions which concern:

a. *processes for cloning human beings*;
   This includes any process, including embryonic division techniques, designed to create a human being with the same genetic identity as another human being.
b. *processes for modifying the germ line genetic identity of human beings;*
   Under Rule 28(1)(b) EPC, processes for modifying the germ line genetic identity of human beings are also excluded. This mainly concerns processes that involve genetically modifying human germ cells which can be passed over to descendants.
c. *uses of human embryos for industrial or commercial purposes;*
   The ban on using human embryos for industrial or commercial purposes does not affect inventions for therapeutic or diagnostic purposes which are applied to and beneficial for the human embryo. Rule 28(1)(c) EPC also prohibits human pluripotent stem cells, uses of these and products derived from them if the products are obtained exclusively by using – and thereby destroying – a human embryo.

This was the case for all human stem cells before the technical teaching of human embryonic stem cells derived from parthenogenetically activated human oocytes was put into practice (5 June 2003).

d. *processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes.*
   The exclusion of the processes and products under Rule 28(1)(d) EPC is intended to be the product of a balancing test for considering animal suffering, medical benefit and the necessary correspondence between the two in terms of the animals in question. The substantial medical benefit referred to as part of the balance includes any benefit in terms of research, prevention, diagnosis or therapy.

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

- 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, OJ EPO 2020, A119).
- 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.

- In contrast, plants or animals produced by a technical process which modifies the genetic characteristics of the plant or animal are patentable.
- 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.
- Targeted mutation, e.g. with CRISPR/Cas, and random mutagenesis, e.g. UV-induced mutation, are both technical processes in this respect. If, when looking at the offspring of transgenic organisms or mutants, the mutation or transgene is present in said offspring, it has not been produced exclusively by an essentially biological method and is thus patentable.

Limiting the scope of a claim by using a "disclaimer" to exclude a technical feature not disclosed in the application as filed may be allowable under Article 123(2) EPC for removing subject-matter which, under Articles 52-57 EPC, is excluded from patentability for **non-technical reasons**.

For example, inserting "non-human" in order to satisfy the requirements of Article 53(a) EPC is allowable (G 1/03 and G 1/16).

Examples

1. Some examples of non-patentable subject-matter related to Rule 28(1)(a) EPC:
   - a process for cloning animals/mammals/primates/humans
   - a process involving human totipotent cells (able to develop into a human organism)
   - a process for duplicating human embryos/fertilised human oocytes

2. Some examples of subject-matter that complies with Rule 28(1)(a) EPC:
   - a process for cloning non-human animals/mammals/primates
   - a process for cloning mice/sheep/horses/cows, etc.
   - a process for cloning animals/mammals, unless this process is a process for cloning humans

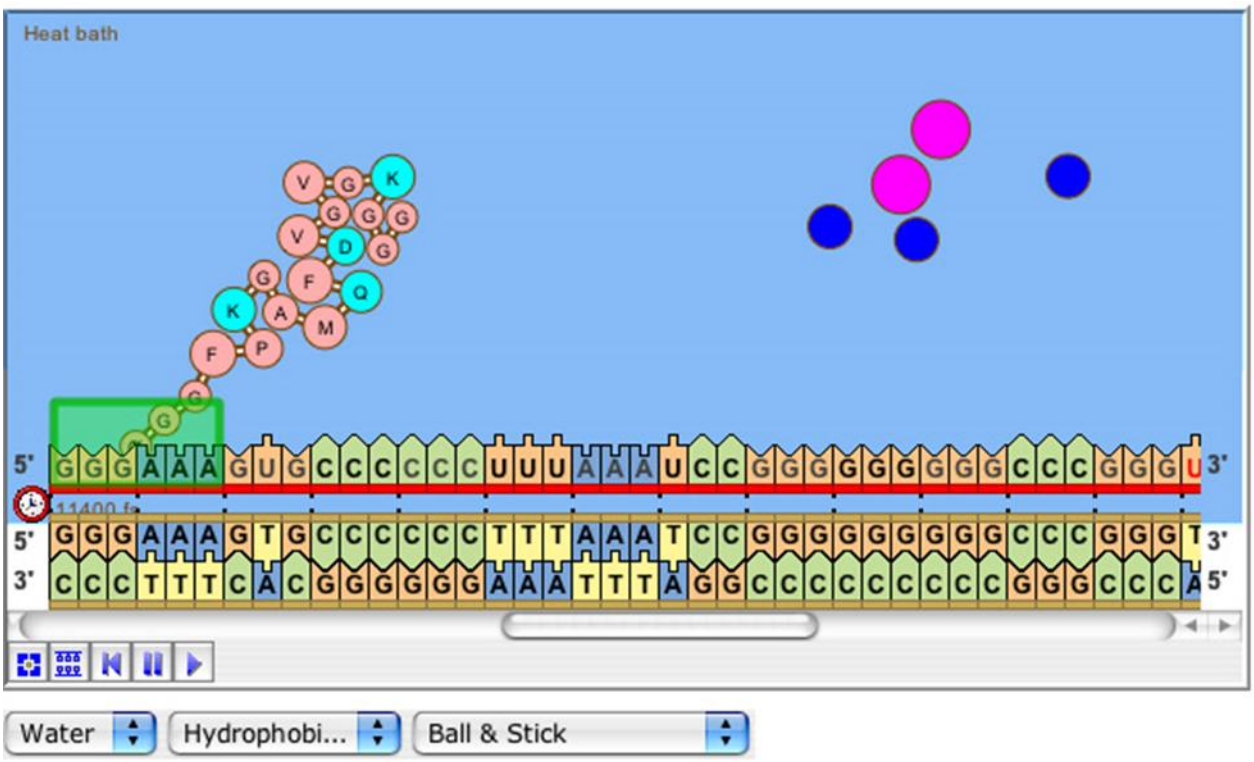
Legal references:

R. 28 EPC, GL G-II, 5.3; GL G-II, 5.4; GL H-V, 4.1, G 1/03; G 2/03; G 1/16

5. Patentability of biological sequences

From DNA to polypeptides:

1. The genes are coded for by the DNA double helix, which consists of two complementary strands.
2. Each strand of DNA contains a chain of connecting nucleotides. Each nucleotide contains a sugar, a nitrogenous base and a phosphate group. There are four different nitrogenous bases in total in DNA: adenine (A), thymine (T), guanine (G) and cytosine (C).
3. The particular sequence of bases is transcribed into messenger RNA (mRNA) molecules, which also have four different nitrogenous bases: adenine, guanine, cytosine and uracil (U).
4. Ribosomes further translate the mRNA sequence into polypeptides, with every three bases coding for a specific amino acid.



Rule 29 EPC refers to the patentability of biological sequences:

- Rule 29(1) EPC warns that "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".
- The spirit of the rule is derived from recital 16 of EU Directive 98/44/EC on biotechnological inventions, which relates to the dignity and integrity of the person and states that a mere discovery cannot be patented.
- Rule 29(2) EPC reads: "An element isolated from the human body or otherwise produced by means of a technical process, 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."
- Importantly, Rule 29(3) EPC notes that "the industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application".

In summary:

1. The simple discovery of the sequence of a gene is not patentable.
2. But the sequence of a gene isolated from the body may be patentable.
3. The industrial application must be disclosed.

This rule is derived from Directive 98/44/EC, recitals 22-24 of which refer to the patentability of biological sequences:

- Recital 22: same criteria of patentability as in all other areas of technology: novelty, inventive step and industrial application; the industrial application must be disclosed in the application as filed
- Recital 23: a mere DNA sequence without indication of a function does not contain any technical information and is therefore not a patentable invention

- Recital 24: in order to comply with the industrial application criterion it is necessary, in cases where a gene is used to produce a protein, to specify which protein is produced and what function it performs

A plausible function must be implicitly or explicitly indicated. Several technical board of appeal decisions are related to this issue:

- T 939/92: molecules for which no activity could be demonstrated would solve only the minimalistic problem of providing "further" molecules (related to a certain structure). The solution to this problem would be an arbitrary selection from among a host of possible alternatives from which the person skilled in the art would choose without exercising any inventive skill.

  Technical problem: providing a further nucleic acid (from a certain tissue or organism) regardless of its likely useful properties (if any).

  Solution: arbitrary selection from a great number of possible nucleic acid molecules; not inventive.
- T 111/00, point 9: "… a specific DNA sequence must be composed of a succession of defined deoxyribonucleotides […] and it cannot be considered inventive for this sole reason. Inventive step could be acknowledged if the specific succession of deoxyribonucleotides imparted some unexpected properties to the molecule".
- T 22/82, point 6: a chemical compound is not patentable "merely because it potentially enriches chemistry"; the structural originality "has no intrinsic value or significance for the assessment of inventive step as long as it does not manifest itself in a valuable property in the widest sense, an effect or an increase in the potency of an effect".

In addition, nucleic acid sequences with no plausible function indicated do not comply with Article 57 EPC in combination with Rule 29(3) and Rule 42(1)(f) EPC. The technical boards of appeal have also ruled on the lack of function and Article 57 EPC in decisions T 870/04, T 898/05 and T 641/05.

In particular, T 870/04 reads: "Merely because a substance (here: a polypeptide) could be produced in some ways does not necessarily mean that the requirements of Article 57 EPC are fulfilled, unless there is also some profitable use for which the substance can be employed" (point 4). It goes on to state: "For the purposes of Article 57 EPC, the whole burden cannot be left to the reader to guess or find a way to exploit an invention in industry by carrying out work in search for some practical application geared to financial gain without any confidence that any practical application exists" (point 19).

Keep in mind that under Article 57 EPC an invention is deemed to be susceptible of industrial application if it can be made or used in any kind of industry, including agriculture.

Examples

Example 1

"A gene coding for a hormone; its function is experimentally demonstrated; this hormone can be used to treat a certain type of disease (efficacy demonstrated in laboratory)."

Patentable, provided all other requirements of the EPC are fulfilled.

Example 2

"ESTs or full-length cDNAs where only the source is indicated (tissue, organism – Human Genome Project), GPCRs, orphan receptors."

Non-patentable – concerns sequences with **no (plausible) function** indicated in the application.

Legal references:
Art. 56 EPC, Art. 57 EPC, R. 29 EPC, R. 42 EPC, T 939/92, T 111/00, T 870/04, EU Dir. 98/44/EC

6. Differences between cosmetic and medical use claims

The exclusion from patentability stipulated in Article 53(c) EPC is the basis for defining what can be an additional differentiating feature over the prior art for the purposes of Article 54(4) and (5) EPC.

Article 54(4) and (5) EPC specify that where a method of treatment using a substance/composition is excluded from patentability under Article 53(c) EPC, the substance/composition for use in a treatment may be **novel** over the prior art **if the use is new**. "Treatment" as per Article 53(c) EPC may be both therapeutic and prophylactic.

However, the limitation that the new use may be a differentiating feature does not apply to substances or compositions for use in a "non-therapeutic" or "cosmetic" use. This can create problems if the scope of the claim is ambiguous as to both use categories. Pursuant to Article 53(c) EPC, the limitation of Article 54(4) and (5) EPC cannot be applied to "non-therapeutic" or "cosmetic" use or method claims. If it is not clear from a claim whether the use is a cosmetic/non-therapeutic use or a medical use, the claim is not clear.

Therefore, for an indication which may have both therapeutic and non-therapeutic aspects (e.g. oral care), it has to be established whether the non-therapeutic/cosmetic use is distinguishable and separable from the therapeutic use.

***If** the therapeutic aspect is **not separable** from the "non-therapeutic" or "cosmetic" use*, it is insufficient to formulate the claim as a "compound/composition for use in a non-therapeutic or cosmetic use". The exclusion from patentability under Article 53(c) EPC cannot be avoided by rewording the claim in purely formal terms to deem the purpose of the method or use, in its indivisible entirety, to be non-therapeutic.

(Decision T 144/83 does not apply; Case Law Book I.B.4..2(a): Inevitable and inextricably linked therapeutic effect of the claimed method.)

***If** the therapeutic aspect is **separable** from the "non-therapeutic" or "cosmetic" use*, then the therapeutic aspects may be claimed as a medical use in the style of Article 54(4) and (5) EPC and the non-therapeutic aspects may be claimed as a non-medical use or method ("e.g. use of compound/composition X for treating …"; "method of treating … with compound/composition X"). This corresponds to the situation underlying decision T 144/83, according to which a *weight loss treatment* to improve bodily appearance was distinguishable as a cosmetic treatment from the (therapeutic) treatment of obesity (see Case Law Book I.B.4..2(b): Therapeutic and non-therapeutic effects distinguishable).

The line may sometimes be difficult to draw. A typical case of "separable" treatments is when the treatments in question involve distinct groups of persons or patients.

The following is a non-comprehensive list of fields where there is notoriously ambiguity:

- hair and scalp treatment
- micro-organisms, oral care, nail care
- UV skin protection, tanning, whitening
- treatment of skin problems
- skin ageing

The following table shows how narrow the line between a therapeutic and a non-therapeutic treatment can be for the field "Hair and scalp treatment":

indication or activity	purely non-therapeutic	purely therapeutic	aspects of both		context-dependent
			not separable	separable	
• removal of scales	x				
• keratolytic activity to assist in removing dandruff scales	x				
• inhibition of cell division to prevent formation of scales	x				
• activity against microorganisms causing dandruff and scalp irritation / itching		x			
scalp itch					x
scalp irritation		x			
seborrheic dermatitis		x			
eczema		x			

Take the example of a claim to a method of promoting weight loss where the description discloses that compound X can be used to reduce body weight in order to both improve bodily appearance and prevent obesity. This claim would not be allowable in view of Article 53(c) EPC.

Non-allowable claim: "A method for promoting weight loss in a subject by administering compound X" (not allowable in view of Article 53(c) EPC).

Separated into two allowable claims:

a. **Non-therapeutic** method for promoting weight loss in a subject by administering compound X.
b. Compound X for use in treating obesity.

Examples

An application relates to a new toothpaste. The new and inventive feature is a colouring agent X in the toothpaste which fades after a certain time to show that teeth have been sufficiently brushed.

Wording such as "A method of brushing the teeth wherein a colouring agent X is used to indicate the brushing time" is nevertheless *therapeutic*.

The wording of the claim is detrimental. A claim worded as "The use of a colouring agent in a toothpaste to indicate brushing time" may be allowable as the *"use … brushing time"* does not relate to the technical effect of a treatment.

A toothpaste with a colouring agent for use in *tooth whitening* per se is non-therapeutic. If the description includes *ONLY* tooth whitening via e.g. application of whitening strips, where teeth are not simultaneously cleaned, then this is not a therapeutic method.

If the description of the application mentions that the tooth whitening agent may be included in a toothpaste or other compositions involving tooth or mouth cleaning, disinfection, etc., then any associated method is therapeutic.

The whitening method may be limited to the "non-therapeutic" method:

"Method of whitening teeth … wherein the paste comprises colouring agent X".

Legal references:
Art. 53(c) EPC, Art. 54 EPC, Art. 84 EPC, GL G-II, 4.2.1, GL G-VI, 6.1.2, GL F-IV, 4.13.3, GL G-VI, 6.1, CL Book I.B.4.4.2

7. Beyond the course

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

- G 3/19 (OJ EPO 2020, A119).

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