

Learning path for patent examiners

Patentability: exceptions and exclusions: Entry level

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Introduction

This publication, "Patentability: exceptions and exclusions, Entry 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 definition and the legal basis of the exceptions to patentability according to the European patent convention.
- The basis for patentable and non-patentable biotechnological inventions
- The importance of assessing the exception as first step in examination in biotech and pharma.
- The principles of the exceptions beyond the EPC.

2. Exceptions to patentability – legal basis

Article 53 EPC defines three exceptions to patentability: (a) inventions the commercial exploitation of which would be contrary to "ordre public" or morality; (b) plant varieties or animal species or essentially biological processes for the production of plants or animals; this does not apply to microbiological processes or their products; (c) methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body; this does not apply to products, in particular substances or compositions, for use in any of these methods.

The exceptions are regarded as inventions, but a European patent will not be granted for a different reason.

The exception to patentability must be assessed as the first step on examination. This is particularly relevant in biotechnology and pharmaceutical inventions where there are many borderline cases.

It must be investigated whether the subject-matter falls within the category of an exception to patentability because there is no point in assessing the patentability, i.e. the novelty, inventive step, industrial applicability, sufficient disclosure and clarity, of subject-matter which is determined to cover an exception to patentability.

At the same time, it must be assessed whether the subject-matter falls within any of the exclusions as per Article 52(2) EPC.

The difference between exceptions and exclusions lies in the definition of an invention. Specifically, discoveries, scientific theories, mathematical methods and aesthetic creations are not regarded as inventions in the European Patent Convention and are therefore excluded under Article 52(2) EPC, whereas, as mentioned above, the exceptions concern inventions for which a European patent will not be granted for different reasons.

Examples

- A process for cloning humans falls under Article 53(a) EPC; a plant variety such as durum wheat type wh222 is not patentable under Article 53(b) EPC.
- Background question to consider: would claimed subject-matter prevent a doctor from treating a patient?

Legal references:

Art. 53 EPC, G 5/83, T 116/85; T 82/93

3. Patentable biotechnological inventions

For European patent applications and patents concerning biotechnological inventions, the relevant provisions of the EPC are to be applied and interpreted in accordance with the provisions of Rules 26-29 EPC.

Rule 26 EPC concerns general remarks and definitions.

Rule 26(1) EPC reads: "For European patent applications and patents concerning biotechnological inventions, the relevant provisions of the Convention shall be applied and interpreted in accordance with the provisions of this Chapter. Directive 98/44/EC of 6 July 1998 on the legal protection of biotechnological inventions shall be used as a supplementary means of interpretation."

The aims of Directive 98/44/EC of the European Parliament and of the Council on the legal protection of biotechnological inventions can be summarised as follows:

- to serve as guidelines about (non-)patentable subject-matter in biotech in the European Union (EU)
- to serve as guidelines about patent management and the scope of protection in the EU
- to achieve harmonisation among EU countries
- to establish a monitoring body/authority within the EU
- to lay down provisions related to the disclosure/availability of biological material

The Directive is drafted as a series of articles and recitals to give legal certainty.

According to Rule 27 EPC, patentable biotechnological inventions may concern:

- a. biological material isolated from its natural environment or produced by technical means. Hence, biological material may be considered patentable even if it already occurs in nature and is not a mere discovery. For example, the discovery of an enzyme having a function in a physiological route without an associated technical character cannot be considered a patentable biotechnological invention
- b. plants or animals, provided the invention is not limited to a particular plant or animal variety and is not obtained by an essentially biological process
- c. a microbiological or other technical process or a resulting product. "Microbiological process" means any process involving or performed upon or resulting in microbiological material, which includes micro-organisms and animal or plant cells that can be cultured independently of the organism they are derived from

Legal references:

Art. 54(b) EPC, R. 26 EPC; R. 27 EPC

4. Non-patentable biotechnological inventions

Rule 28(1) EPC lists a number of non-patentable biotechnological inventions as follows:

- 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;

This mainly concerns the 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 a human embryo and if the isolation of the stem cell from the embryo harms the 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 result 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.

- a. 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).
- b. 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.
- c. In contrast, plants or animals produced by a technical process which modifies the genetic characteristics of the plant or animal are patentable.
- d. 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.
- e. Transgenic plants and mutants induced by technical means are thus patentable, while the products of conventional breeding are not.

- f. 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.

Legal references:

R. 28 EPC, GL G-II, 5.4

5. Morality and "ordre public"

Article 53 EPC governs the exceptions to patentability under the EPC. (Keep in mind that the exceptions are regarded as inventions for which a European patent will not be granted.)

Under Article 53(a) EPC, any invention the commercial exploitation of which would be contrary to "ordre public" or morality is specifically excluded from patentability. The purpose of this is to deny protection to inventions likely to lead to riots, public disorder or criminal or other generally offensive behaviour. Anti-personnel mines are an obvious example.

This provision is likely to be invoked only in rare and extreme cases. A fair test to apply is to consider whether the public in general is likely to deem the invention so abhorrent that the grant of patent rights would be inconceivable. If this is clearly the case, an objection is raised under Article 53(a) EPC; otherwise no objection is raised. More frequent cases arise in the area of biotechnological inventions, with Rule 28(1) EPC listing a number of examples.

To interpret and assess morality and "ordre public", we follow European standards based on

- the EU Convention on Human Rights, according to decision T 866/01
http://europa.eu/legislation_summaries/glossary/human_rights_en.htm
- the Council of Europe's Convention on Human Rights and Biomedicine
<http://conventions.coe.int/treaty/en/treaties/html/164.htm>
- the EU Charter of Fundamental Rights
http://www.europarl.europa.eu/charter/default_en.htm
- international human rights treaties

The technical boards of appeal (T 356/93) have defined European standards as follows:

- The issue of morality and "ordre public" was raised in T 356/93 in connection with plants. The object of the invention was plants and seeds resistant to a particular class of herbicides so that they could be selectively protected against weeds and fungal diseases. This was achieved by stably integrating into the genome of the plants a heterologous DNA encoding a protein capable of deactivating or neutralising the herbicides. The patent was opposed under Article 53(a) EPC 1973, in particular on the grounds that the exploitation of the invention was likely to cause serious damage to the environment.
- The board defined the concept of "ordre public" as covering the protection of public security and the physical integrity of individuals as part of society. According to the board, it also encompassed the protection of the environment, so inventions the exploitation of which was likely to seriously prejudice the environment were to be excluded from patentability as being contrary to "ordre public". However, a decision in this respect presupposes that the threat to the environment be sufficiently substantiated at the time the decision is taken by the EPO.

- The board held that the concept of morality was related to the belief that some behaviour was right and acceptable whereas other behaviour was wrong, this belief being founded on the totality of the accepted norms which were deeply rooted in a particular culture. For the purposes of the EPC, the culture in question was the culture inherent in European society and civilisation. Accordingly, inventions the exploitation of which was not in conformity with the conventionally accepted standards of conduct pertaining to this culture were to be excluded from patentability as being contrary to morality.
- The board found that none of the claims related to subject-matter which could lead to a misuse or destructive use of plant biotechnological techniques because they concerned activities (production of plants and seeds, protection of plants from weeds or fungal diseases) and products (plant cells, plants, seeds) which could not be considered to be wrong as such in the light of the conventionally accepted standards of conduct in European culture. Plant biotechnology per se could not be regarded as being more contrary to public morality than traditional selective breeding.

Examples

Anti-personnel mines are an obvious example of inventions against morality.

Legal references:

Art. 53(a) EPC, R. 28(1) EPC, T. 356/93

6. Discoveries and presentations of information

Discoveries and presentations of information are not regarded as inventions under Article 52(2)(a) and (d) EPC:

- Discoveries are abstract items.
- Presentations of information are not technical.

An invention within the meaning of the EPC must both be concrete and have technical character.

The EPC does not define what is meant by "invention", but Article 52(2) EPC contains a non-exhaustive list of things which are not regarded as inventions. Note that the items on this list are all abstract (e.g. discoveries or scientific theories) and/or non-technical (e.g. aesthetic creations or presentations of information). This is contrary to the definition of an "invention" within the meaning of Article 52(1) EPC, i.e. that it must both be concrete and have technical character.

If a new property of a known material or article is found, that is a mere discovery and is unpatentable because a discovery as such has no technical effect and is therefore not an invention within the meaning of Article 52(1) EPC. If, however, that property is put to practical use, then this constitutes an invention which may be patentable. For example, the discovery that a particular known material is able to withstand mechanical shock would not be patentable, but a railway sleeper made from that material could well be. Finding a previously unrecognised substance occurring in nature is also a mere discovery and therefore unpatentable.

However, if a substance found in nature can be shown to produce a technical effect, it may be patentable. One example is that of a substance occurring in nature which is found to have an antibiotic effect. In addition, if a micro-organism is discovered to exist in nature and to produce an antibiotic, the micro-organism itself may also be patentable as one aspect of the invention.

Similarly, a gene which is discovered to exist in nature may be patentable if a technical effect is revealed, e.g. its use in making a certain polypeptide or in gene therapy.

Discovery or invention – conclusions:

- A discovery is cognitive in nature: finding a plant, finding a mineral, etc.
- An invention always has to be technical in nature, involving reproducible technical teaching (isolation, purification, characterisation, technical effect suggesting a use).
- An invention has to solve a meaningful technical problem (Article 56 EPC) and be industrially applicable (Article 57 EPC).

Examples

1. Is penicillin a discovery or an invention?

- Merely finding something that already exists in nature is a discovery, e.g. contamination with mould kills bacteria.
- If a technical character is associated with this finding, then this finding can be regarded as an invention, e.g. isolated fungus, means for culturing it, isolated antibiotic agent.

2. Inventions/discoveries or presentations of information claimed as

- a DNA sequence
- an amino acid sequence
- an expression profile/an expression pattern related to certain gene(s)/an activity graph
- a database containing sequences
- a data carrier containing sequences

cannot be deemed more than a discovery or presentation of information.

whereas

- a DNA molecule comprising the nucleotide sequence
- a polypeptide comprising the amino acid sequence
- a gene characterised by an expression profile/an expression pattern

can be regarded as inventions,

Legal references:

Art. 52(2)(a)-(d) EPC, Art. 57 EPC, R. 26 EPC; R. 29(1) EPC, GL G-II,1; GL G-II, 3.1

7. Methods of treatment

Article 53(c) EPC states: "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; this provision shall not apply to products, in particular substances or compositions, for use in any of these methods." The second part of Article 53(c) EPC (i.e. "this provision shall not apply to **products**, in particular substances or compositions, **for use** in any of these methods") forms the basis for the medical use claims under Article 54(4) and (5) EPC.

The **purpose** of Article 53(c) EPC is to safeguard the principle whereby medical and veterinary practitioners have the freedom to use the best available treatments to the benefit of their patients, uninhibited by any worry that some treatment might be covered by a patent (G 5/83, G 1/04, G 1/07).

To be excluded from patentability, a treatment or diagnostic method must actually be carried out on the **living human or animal body**. A treatment or diagnostic method practised on a dead human or animal body would therefore not be excluded from patentability under Article 53(c) EPC. The provisions apply to humans and animals alike and it is irrelevant who or what is performing the method, i.e. medical or non-medical staff or surgical robots.

The following are some examples that are either excluded or allowable under Article 53(c) EPC.

Excluded:

- **relieving discomfort** caused by menstruation by administering an appropriate agent (T.81/84)
- **controlling parasitic infestations** in pigs by applying a pesticide to the pig's body surface (T.116/85)
- **returning processed blood**, depleted of some of its components and charged with an anticoagulant (T.1075/06)

Allowable:

- **measuring the flow of a liquid** in an **implantable device** for controlled drug administration (T.245/87)
- **non-therapeutic use** of a medication to increase the **milk production** in cows (T.774/89)
- use of a substance **against irritating snoring** (T.584/88)
- testing the **efficiency of sunscreens** (T.619/03)
- **treating blood for storage** in a blood bank or diagnostic testing of blood samples

Legal references:

Art. 53 (c) EPC, GL G-II, 4.2, CL Book I.B.4.1

8. Beyond the course

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

- EU Convention of Human Rights
http://europa.eu/legislation_summaries/glossary/human_rights_en.htm
- The Council of Europe's Convention of Human Rights and Biomedicine
<http://conventions.coe.int/treaty/en/treaties/html/164.htm>
- EU Charter of Fundamental Rights
http://www.europarl.europa.eu/charter/default_en.htm

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