

**PART II****SUBSTANTIVE PATENT LAW****Chapter I****Patentability****Article 52****Patentable inventions**

**Content of Article 52 (4)  
moved to Article 53 (c)**

(1) European patents shall be granted for any inventions, in all fields of technology, provided that they are new, involve an inventive step and are susceptible of industrial application.

(2) The following in particular shall not be regarded as inventions within the meaning of paragraph 1:

- (a) discoveries, scientific theories and mathematical methods;
- (b) aesthetic creations;
- (c) schemes, rules and methods for performing mental acts, playing games or doing business, and programs for computers;
- (d) presentations of information.

(3) Paragraph 2 shall exclude the patentability of the subject matter or activities referred to therein only to the extent to which a European patent application or European patent relates to such subject matter or activities as such.

**Comment:**

Article 52 (1) EPC now refers to granting patents for inventions “in all fields of technology”, bringing the wording into line with the first sentence of Article 27 (1) of the TRIPS agreement.

This amendment provides a clear legal basis for the EPO’s current approach to assessing patentable subject matter, which only allows patents for inventions that have “technical character”, involve “technical teaching” or can be said to provide “technical solutions” to “technical problems”. As is reflected by the applicability of the amendment to all European patents or patent applications regardless of when filed or granted, the change is not expected to have any effect on substantive practice.

Article 52 (4) EPC has been deleted and its contents have been transferred to Article 53 EPC (*see commentary below*).

Case law on what constitutes a “patentable” invention may be found in the *Case Law of the Boards of Appeal of the European Patent Office*, section I – A.1, pages 1-20. Article 52 EPC is also discussed in the *Guidelines for Examination in the European Patent Office*, Part C, Chapter IV, sections 1 and 2.

**Article 53**  
**Exceptions to patentability**

European patents shall not be granted in respect of:

- (a) 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;
- (b) 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;
- (c) methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body; this provision shall not apply to products, in particular substances or compositions, for use in any of these methods.

No genetically modified humans, clones or commercial use of embryos – **Rule 28**

Definition of biotechnological inventions – **Rules 26 and 27**

Mere discovery of human gene not patentable – **Rule 29 (1)**

**Article 53 (c) previously Article 52 (4)**

**Related Rules**

**Rule 26**  
**General and definitions**

**Previously Rule 23b**

(1) 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.

(2) "Biotechnological inventions" are inventions which concern a product consisting of or containing biological material or a process by means of which biological material is produced, processed or used.

(3) "Biological material" means any material containing genetic information and capable of reproducing itself or being reproduced in a biological system.

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

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

(5) A process for the production of plants or animals is essentially biological if it consists entirely of natural phenomena such as crossing or selection.

(6) "Microbiological process" means any process involving or performed upon or resulting in microbiological material.

Previously Rule 23c

**Rule 27****Patentable biotechnological inventions**

Biotechnological inventions shall also be patentable if they concern:

- (a) biological material which is isolated from its natural environment or produced by means of a technical process even if it previously occurred in nature;
- (b) plants or animals if the technical feasibility of the invention is not confined to a particular plant or animal variety;
- (c) a microbiological or other technical process, or a product obtained by means of such a process other than a plant or animal variety.

Previously Rule 23d

**Rule 28****Exceptions to patentability**

**Article 53 (a)** – Exceptions to patentability

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

- (a) processes for cloning human beings;
- (b) processes for modifying the germ line genetic identity of human beings;
- (c) uses of human embryos for industrial or commercial purposes;
- (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.

Previously Rule 23e

**Rule 29****The human body and its elements**

- (1) 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.
- (2) 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.
- (3) The industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application.

**Comment:**

Minor editorial amendments have been made to Article 53 (a) EPC to align the wording with Article 27.2 of TRIPS and Article 6.1 of the EU Directive on the Legal Protection of Biotechnology Inventions. In particular, Article 53 (a) EPC now refers to “commercial exploitation” rather than “publication or exploitation” as the backdrop against which to assess whether an invention is contrary to *ordre public* or morality.

The exclusion of methods of treatment and diagnostic methods in old Article 52 (4) EPC has been transferred to Article 53 EPC. Previously, while surgical or therapeutic methods were accepted as inventions, old Article 52 (4) EPC excluded them from patentability on the basis of the fiction that such inventions were not industrially applicable. Moving the exclusion to Article 53 EPC clarifies that in reality diagnostic and

therapeutic methods are excluded from patentability for public policy reasons. No change of practice is expected to arise from this amendment.

The special rules relating to biotechnological inventions are now found in Rules 26 and 27 EPC. These define biotechnological inventions and provide that they are patentable if they involve either the isolation of biological material from its natural environment or biological material produced by means of a technical process even if it previously occurred in nature (*Rule 27 (a) EPC*). Certain biotechnological inventions are expressly excluded from patentability, including processes for cloning human beings or modifying human germ lines, inventions involving human embryos and inventions that cause suffering to animals without there being any substantial medical benefits to man or animal (*Rule 28 EPC*). Parts of the human body are also excluded from patentability (*Rule 29 (1) EPC*) as is the patenting of human gene sequences where an industrial application of the sequence is not also disclosed (*Rule 29 (3) EPC*). These rules correspond to their counterparts in the EPC prior to its revision.

In general the exclusions from patentability in Article 53 EPC have been construed narrowly. "Diagnostic methods" and "practised on the human or animal body" were considered in **G1/04**, in which the Enlarged Board of Appeal held that a claim would only fall within the exclusion if it included a diagnostic step and essential preceding steps involving interactions with the human or animal body. Similarly, the term "plant variety" was considered in **G1/98**, in which the Enlarged Board held that a claim was only excluded from patentability under Article 53 (b) EPC if it covered a single plant variety. If the claim covered multiple plant varieties, it was not so excluded.

Case law on medical methods excluded from patentability may be found in the *Case Law of the Boards of Appeal of the European Patent Office*, section I-A.2, pages 20-37. Case law on the other types of inventions excluded from patentability can be found in the *Case Law of the Boards of Appeal of the European Patent Office*, section I-B, pages 37-45. Biotechnological inventions are discussed in the *Guidelines for Examination in the European Patent Office*, Part C, Chapter IV, section 3. Exceptions to patentability are discussed in the *Guidelines for Examination in the European Patent Office*, Part C, Chapter IV, section 4.

### **Article 54** **Novelty**

- (1) An invention shall be considered to be new if it does not form part of the state of the art.
- (2) The state of the art shall be held to comprise 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.
- (3) Additionally, the content of European patent applications as filed, the dates of filing of which are prior to the date referred to in paragraph 2 and which were published on or after that date, shall be considered as comprised in the state of the art.
- (4) Paragraphs 2 and 3 shall not exclude the patentability of any substance or composition, comprised in the state of the art, for use in

Non-prejudicial disclosures – **Article 55**

For the purposes of **Articles 54 (2) and (3)**, "date of filing" means priority date, if priority claimed – **Article 89**

Earlier European patent abstract not prior art – **Article 85**

Publication of European patent application – **Article 93**

Earlier PCT is prior art only if regional phase entered – **Rule 165**

**N.B. Article 54 (4) of the EPC 1973 continues to apply to patents and patent applications filed before the coming into force of the EPC 2000 (see commentary below)**

**Article 53 (c)** – Surgery, therapy and diagnostic methods

a method referred to in Article 53 (c), provided that its use for any such method is not comprised in the state of the art.

(5) Paragraphs 2 and 3 shall also not exclude the patentability of any substance or composition referred to in paragraph 4 for any specific use in a method referred to in Article 53 (c), provided that such use is not comprised in the state of the art.

**New Rule**

**Article 54 (3)** – Prior art effect of earlier European patent applications

**Article 153 (3)** – Publication of PCT application in English, French or German

**Article 153 (4)** – Filing and publication of translation of PCT application into English, French or German

**Rule 159 (1)(c)** – Filing fee for entry of Euro-PCT application into regional phase

**Related Rule**

**Rule 165**

**The EuroPCT application as conflicting application under Article 54, paragraph 3**

A Euro-PCT application shall be considered as comprised in the state of the art under Article 54, paragraph 3, if in addition to the conditions laid down in Article 153, paragraph 3 or 4, the filing fee under Rule 159, paragraph 1 (c) has been paid.

**Other Relevant Rules**

Rule 159 The European Patent Office as a designated or elected Office – Requirements for entry into the European phase See Article 153, page 178

**Comment:**

The novelty of a European patent application is assessed against the state of the art as of its filing date, or, if priority is claimed, its priority date (*Article 54 (1) and Article 89 EPC*). The “state of the art” is defined by Article 54 (2) EPC as everything made available to the public by means of a written or oral description, by use, or in any other way.

Additionally, Article 54 (3) EPC provides that for the purposes of assessing novelty, later published European patent applications having earlier priority or filing dates also form part of the state of the art. Previously, later published European patent applications having earlier priority or filing dates were only considered part of the state of the art to the extent that the same Contracting States were designated in the earlier and later applications. This restriction has been dropped and later published European patent applications having priority or filing dates earlier than the filing or priority dates of European patent applications filed after the EPC 2000 comes into force will be considered prior art for the assessment of novelty in respect of all Contracting States.

The change does not affect patent applications filed prior to implementation of the EPC 2000. For such applications and granted patents based on them, old Article 54 (4) EPC continues to apply. This section read:

(4) Paragraph 3 shall be applied only in as far as a Contracting State designated in respect of the later application, was also designated in respect of the earlier application as published.

In relation to the old law, the Enlarged Board of Appeal in **G4/98** held that the Contracting States indicated on an application when published were determinative as to the Article 54 (3) prior art effect of an earlier European patent application, regardless whether designations subsequently lapsed due to non-payment of designation fees.

Article 54 (4) EPC corresponds to former Article 54 (5) EPC but has been amended to take account of the transfer of provisions excluding surgical, therapeutic and diagnostic methods from patentability. These provisions were previously in Article 52 (4) EPC but are now in Article 53 (c) EPC.

Article 54 (5) is new and has been introduced to provide an explicit basis for claims based on the discovery of new uses for medical products. Previously the acceptability of such claims was based on Enlarged Board of Appeal decisions **G1/83**, **G5/83** and **G5/83**.

In **G1/92**, the Enlarged Board of Appeal held that making a substance publicly available makes its composition also available, irrespective of whether there are reasons to analyse the composition. The test for novelty is therefore entirely objective and there is no requirement for evidence that anyone would be motivated to undertake a compositional analysis.

Case law on the definition of novelty may be found in the *Case Law of the Boards of Appeal of the European Patent Office*, section I – C, pages 46-119. The definition of novelty in Article 54 EPC is discussed in the *Guidelines for Examination in the European Patent Office*, Part C, Chapter IV, sections 6 to 9.

### **Article 55**

#### **Non-prejudicial disclosures**

(1) For the application of Article 54, a disclosure of the invention shall not be taken into consideration if it occurred no earlier than six months preceding the filing of the European patent application and if it was due to, or in consequence of:

- (a) an evident abuse in relation to the applicant or his legal predecessor, or
- (b) the fact that the applicant or his legal predecessor has displayed the invention at an official, or officially recognised, international exhibition falling within the terms of the Convention on international exhibitions signed at Paris on 22 November 1928 and last revised on 30 November 1972.

(2) In the case of paragraph 1 (b), paragraph 1 shall apply only if the applicant states, when filing the European patent application, that the invention has been so displayed and files a supporting certificate within the time limit and under the conditions laid down in the Implementing Regulations.

**Article 54** – Assessment of novelty

Supporting certificate for international exhibition due within 4 months of filing European patent application  
– **Rule 25**

#### **Related Rule**

##### **Rule 25** **Certificate of exhibition**

Within four months of filing the European patent application, the applicant shall file the certificate referred to in Article 55, paragraph 2, which:

**Previously Rule 23**

**Article 55 (2)** – Certificate for international exhibition