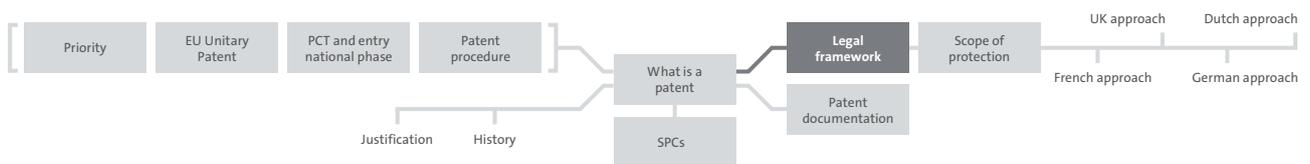


Legal framework

Essentials: Legal framework



Patentable subject-matter

According to Article 27(1) of the TRIPS Agreement, “patents shall be available for any inventions, whether products or processes, in all fields of technology”. The Agreement does not define what is meant by either “inventions” or “technology”. Legislators therefore have considerable leeway in defining what constitutes patentable subject-matter.

Most jurisdictions have chosen to follow the principle of exclusion rather than attempting to define the terms “invention” and “technology”. According to Article 52(2) EPC, the following in particular are not to be regarded as inventions:

- Discoveries, scientific theories and mathematical methods
- Aesthetic creations
- Schemes, rules and methods for performing mental acts, playing games or doing business, and programs for computers
- Presentations of information.

It should, however, be noted that patentability is excluded only to the extent to which the patent or patent application relates to such subject-matter or activities as such. This is why, for example, computer programs may still be subject to European patents and European patents with unitary effect (unitary patents), as long as the program is not patented “as such”.

Most laws have traditionally defined inventions as comprising “technical aspects”, solving a “technical problem” or exhibiting a “technical effect”. The TRIPS Agreement, which sets out the minimum standards of protection to be provided, does not include this specification.

Technical character

Having technical character is an implicit requirement of the EPC to be met by an invention in order to be an invention within the meaning of Article 52(1) EPC. For example, methods only involving economic concepts and practices of doing business are not inventions within the meaning of Article 52(1) EPC. A feature of a method which concerns the use of technical means for a purely non-technical purpose and/or for processing purely non-technical information does not necessarily confer a technical character on such a method. (see decision T 931/95 of the Boards of Appeal of the EPO).

The same is true of the EPC. The wording of Article 52(1) EPC reserves patent protection for creations in the technical field. In order to be patentable, the subject-matter claimed must involve a technical teaching, i.e. an instruction addressed to a skilled person as to how to solve a particular technical problem using particular technical means. Thus, an invention satisfies Article 52(1) EPC if, for example, a technical effect is achieved by it or if technical considerations are required to carry it out.

Exclusions from patentability

Certain inventions may be excluded from patentability. The only grounds explicitly mentioned in the TRIPS Agreement are those of Article 27(2) and (3) and Article 73. The grounds mentioned in Article 27 are mirrored in Article 53 EPC, which states that European patents are not to be granted in respect of:

- Inventions the commercial exploitation of which would be contrary to *ordre public* or morality.
- Plant or animal varieties or essentially biological processes for the production of plants or animals.
- Methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the body.

It is worth noting that the exclusion of certain methods for treatment of the human or animal body by surgery or therapy and diagnostic methods does not mean that tools for the treatment of human or animal bodies are excluded from patent protection. This applies in particular to drugs and medical devices.

Article 73(b) of the TRIPS Agreement allows states to take any action considered necessary for the protection of essential security interests. Further exclusions may eventually be derived from the grounds mentioned in Articles 7 and 8 of the Agreement.

Animals and plants

Although patents are excluded for single animal or plant varieties (or species), they can nevertheless be granted if these varieties fall within the scope of the patent claims (see decision T 315/03 of the Boards of Appeal of the EPO). If plant varieties are excluded from patent protection, states must ensure that they are protected by a *sui generis* system of protection (see the International Convention for the Protection of New Varieties of Plants).

Patentable inventions

In order to qualify for a patent, inventions must fulfil the requirements of patentability. According to Article 27 of the TRIPS Agreement, patents must be available for all inventions provided that they

- are new,
- involve an inventive step and
- are capable of industrial application.

These requirements are mirrored in Article 52(1) EPC. Evaluating the merit of an invention in the light of these standards is by no means an easy task. The examination of novelty is an objective exercise. According to Article 54 EPC, an invention is considered novel if it does not form part of the state of the art, i.e. if it has never been made available to the public anywhere in the world by means of a written or oral description, by use, or in any other way.

Article 55 contains a list of non-prejudicial disclosures:

- an evident abuse in relation to the applicant or his legal predecessor, or
- the fact that the applicant or his legal predecessor has displayed the invention at an official, or officially recognised, international exhibition.

Unlike the US or Japan, the European patent system currently does not provide for a grace period (usually between 6 and 12 months) that would allow inventors to disclose their invention to the public before filing a patent. Hence, even disclosures of the invention by the inventor himself may destroy novelty.

The appraisal of industrial application also rarely poses a problem. Inventions are capable of industrial application within the meaning of Article 57 EPC if they can be made or used in any kind of industry, including agriculture. An actual use for the invention is, however, not required.

Inventive step, on the other hand, is more difficult to assess and is inherently subjective. Article 56 EPC states that an invention is to be considered as involving an inventive step if, having regard to the state of the art, it is not obvious to a person skilled in the art. Having read the patent and the prior art cited against it, patent examiners and judges must therefore put themselves in the shoes of a hypothetical skilled man or “person skilled in the art”, who knows everything about the state of the art but does not have the slightest spark of inventive ingenuity. From that perspective, they must decide whether the skilled person would have made the step from the prior art to the invention claimed in the patent.

Indicators of non-obviousness have been developed in the case law. An invention is deemed non-obvious if it

- yields an unexpected technical effect,
- offers a technical advantage despite a teaching away in the prior art, or
- solves a technical problem which workers in the art have been attempting to solve for a long time, or otherwise fulfils a long-felt need.

The commercial success of an invention is, however, generally not an indicator of inventiveness.

Disclosure

According to Article 29 of the TRIPS Agreement, an applicant for a patent must disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art. This is the *quid pro quo* principle of patent protection. In exchange for disclosing his invention to others for use after 20 years, instead of keeping it secret, the patentee is granted a temporary right to exclude others.

The disclosure formalities are mirrored in Article 83 EPC. Insufficient disclosure leads to the rejection of the patent application, and is also a ground for opposition under Article 100 EPC or for invalidity proceedings (in the case of granted patents).

Exclusive rights conferred by a patent

A patent confers upon its owner the right to prevent the direct and indirect use of the protected invention by any third party not having his consent.

This includes the following exclusive rights:

- making the invention
- offering it
- placing it on the market
- using it
- storing it
- importing it.

Export

Note that mere export does not fall under the exclusive rights conferred by the patent.

The precise scope of these rights is not defined in the law, so it is up to the national courts to determine whether a specific conduct infringes the patent owner's rights. This may involve delicate assessments, especially in the area of cross-border trade (e.g. the question whether the transit through and temporary storage of goods in a country where these goods are protected before being transported to a country where they are not protected constitutes patent infringement within the country of transit).

The same exclusive rights apply if the invention consists of a process.

The patent owner has the right to prevent third parties from

- using the process
- offering it for use.

The outcome of a patented process is also protected. Third parties are not allowed to

- offer, place on the market, use or import or
- store for those purposes

products obtained by a patented process. The alleged infringer may, however, rebut the presumption that his product is obtained by the patent process by demonstrating that he is using a process which does not fall within the scope of the patent. In this regard the burden of proof may be on the alleged infringer.

Furthermore, patentees have the right to prevent the indirect use of their inventions. Without the patent holder's consent, third parties may not

- supply or
- offer to supply

any person other than a party entitled to exploit the invention, such as the patent holder and his licensees.

Scope of protection

The patent holder may only invoke his exclusive rights within the scope of protection granted. According to Article 69 EPC, the scope (or extent) of the protection conferred by a European or unitary patent is to be determined by the claims, which are to be interpreted using the description and drawings.

The Protocol on the Interpretation of Article 69 provides clarification on the matter. It states that the extent of protection is not to be understood as that defined by the strict, literal meaning of the wording used in the claims, and that the description and drawings are employed solely for the purpose of resolving any ambiguity found in the claims. Nor should it be taken to mean that the claims serve only as a guideline and that the actual protection conferred may extend to what, from a consideration of the description and drawings by a person skilled in the art, the patent proprietor has contemplated. On the contrary, it is to be interpreted as defining a position between these extremes which combines a fair protection for the patent proprietor with a reasonable degree of legal certainty for third parties.

Patent claims consist of specific features of the invention. An assessment as to whether a third party has infringed the patent may be based on a feature analysis, which comprises all the features of the patent claim in a sort of list. The patent is infringed only if all the features of the claim are fulfilled. The existence of further features in the alleged infringing conduct does not rule out infringement.

Infringement is at present a matter for the national courts.

Exceptions to exclusive rights

Certain acts and forms of use are, however, excluded from the exclusive rights conferred by patents.

According to Article 27 of the UPC Agreement, which applies to both European and unitary patents (provided that the Agreement has been ratified in the country for which the European patent is issued), this includes:

- Acts done privately and for non-commercial purposes.
- Acts done for experimental purposes relating to the subject-matter of the patented invention.
- The use of biological material for the purpose of breeding, or discovering and developing other plant varieties.
- Studies, tests and trials conducted with a view to obtaining market authorisation for generic medicinal products.
- The extemporaneous preparation by a pharmacy, for individual cases, of a medicine in accordance with a medical prescription or acts concerning the medicine so prepared.
- The use of patented inventions on board vessels or in the construction or operation of aircraft or land vehicles or other means of transport, when they temporarily or accidentally enter the country in which the patent has effect.
- The use by a farmer of the product of his harvest for propagation or multiplication on his own holding, or of protected livestock for an agricultural purpose, provided that these materials were sold or otherwise commercialised to the farmer by or with the consent of the patent holder.
- Certain acts performed by the acquirer of a computer program (such as error correction, back-up copies, observing, studying or testing the functioning of the program).
- The decompilation of computer programs with a view to achieving interoperability.
- The propagation or multiplication of biological material placed on the market by the holder of the patent or with his consent.

Applicable law

Patent holders may opt out of the “exclusive jurisdiction” of the UPC with regard to European patents (without unitary effect), but the substantive law set out in the UPC Agreement, including the provision on limitations to the effect of a patent (see Article 27 of the UPC Agreement), remains applicable.

Furthermore, the effect of a patent may not extend to legitimate prior uses of its subject-matter (Article 28 of the UPC Agreement). In countries where prior user rights are available, the patent holder may not enforce his rights against a person who, at the time of filing the application, had already begun to use the invention (usually in secret, since otherwise the patent might not be granted anyway for lack of novelty) or had made the necessary arrangements to do so. This person will be entitled to continue using the invention for the needs of his own business to the same extent that he used it before the patent application was filed.

Such exceptions, as well as compulsory licences and other limitations to patent protection, are not an exception to patent protection, but recognition of important countervailing rights and interests.

Exhaustion of rights

Within the European Union, European and unitary patents are subject to regional exhaustion. This means that the rights conferred by a European or unitary patent do not extend to acts concerning a product covered by that patent after that product has been placed on the market in the European Union by, or with the consent of, the patent proprietor, unless there are legitimate grounds for the patent proprietor to oppose further commercialisation of the product.

National patents remain subject to national exhaustion.

Compulsory licences

In order to accommodate the public interest and confine exclusivity within reasonable limits, states may grant what are known as “compulsory licences”. There are two types of compulsory licence. First, there are compulsory licences which ensure that patents themselves do not become barriers to legitimate invention and innovation. These include compulsory licences

- For improvement inventions (i.e. when a later patent cannot be exploited without infringing an earlier patent).
- For enabling the use of biotechnological inventions as research tools.
- As a remedy against the abuse of patent rights.

Secondly, compulsory licences may also be issued to accommodate other important public interests, such as public health and nutrition, security and environmental protection, or when the demand for the invention is not being adequately satisfied by the patent holder (or his licensee).

Government use

In cases of public interest, states may also invoke the use of patented inventions by the government or by third parties authorised by the government. According to German law, for example, a patent has no effect if the federal government orders that the invention is to be used in the interest of public welfare.

Enforcement: the UPC

Once ratified, the Unified Patent Court (UPC) will be competent for the enforcement of European and unitary patents. It will have exclusive competence in respect of actions

- For actual or threatened infringement and related defences, including counterclaims.
- For declarations of non-infringement.
- For provisional/interim and protective measures and injunctions.
- For revocation and counterclaims for revocation of patents.
- For damages or compensation resulting from the grant of provisional protection.
- Relating to prior user rights.
- For compensation for the grant of licences of right.
- Concerning decisions of the European Patent Office in carrying out administrative tasks in relation to unitary patents.

The UPC Agreement contains transitional provisions regarding the UPC's jurisdiction for European patents (Article 83). During a transitional period of seven years after the date of entry into force of the Agreement, actions for infringement or revocation of a European patent may still be brought before national courts or other competent authorities. In order to avoid the UPC from the outset, proprietors of European patents filed within the transitional period may **opt out** from the exclusive competence of the UPC (unless an action has already been brought before the UPC), in which case the national courts will remain competent for any actions related to such European patents.

National patents granted by national offices remain subject to national law and jurisdiction.

Both the national courts and the UPC are bound by the **Enforcement Directive (2004/48/EC)**, which is concerned with civil law measures, procedures and remedies relating to the enforcement of patent rights.

The Directive includes procedures covering effective means of obtaining and preserving evidence (Section 2). It refers to remedies available to right holders, such as the destruction, recall or permanent removal from the market of illegal goods, as well as to financial compensation, injunctions and damages (Sections 4 to 6). It also includes rules about those entitled to apply to the courts, the presumption of ownership (Articles 4 and 5 of the Directive) and legal costs (Article 14). Finally, the Directive calls for an appropriate balance among all interests involved, including those of right holders, commercial users, consumers, intermediaries and potentially innocent infringers. It not only protects right holders but also contains safeguards and limitations to protect the interests of those who have unknowingly been involved in illegal practices and/or would suffer disproportionately from the results of infringement.

Enforcement must be fair and equitable and should not be unnecessarily complicated or costly, or entail unreasonable time limits or unwarranted delays. It must also be effective, proportionate and dissuasive, and must be applied in such a manner as to avoid the creation of barriers to legitimate trade and to provide for safeguards against the abuse of patent rights.