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The information is not meant to be a comprehensive study or to provide legal advice. The references to European and national law and case law in this manual are presented for training and linguistic purposes and therefore are not meant to be substantive statements concerning patent litigation nor should they be considered the latest jurisprudence.

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Introduction

The overall aim of the EPO's cooperation with its member states is to provide the users of the European patent system with relevant and high-quality patent-related services, to strengthen the European Patent Network and to promote the interoperability of the EPO and the stakeholders of the European patent system.

To this end, the European Patent Academy, in cooperation with Principal Directorate European and International Cooperation, launched a languages training programme consisting of two projects: general language training and patent terminology training. The patent terminology training programme provides inter alia reference materials for further study of patent-related terminology. Manuals have been developed in co-operation with the three main language institutes (British Council, Institut français, Goethe-Institut) for all stakeholders of the European patent system including the EPO bodies, examiners in national patent offices, and professional representatives.

The Judicial Training area of the European Patent Academy supports and develops training initiatives aimed at harmonising patent enforcement and litigation practice in Europe. This manual has been developed in co-operation with EPLAW, the European Patent Lawyers' Association, and provides a unique overview of all aspects relating to patent litigation, both substantive and procedural, that arise in disputes. Additionally, you will find an annexed glossary with patent-related terminology in all three of the EPO's official languages.

This manual will be of interest for judges, patent attorneys, lawyers, academics, and legal staff of IP institutions.

The European Patent Academy

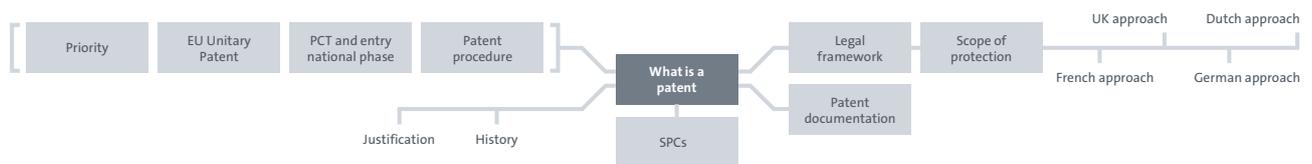
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What is a patent?

Essentials: Patent fundamentals



Basic definition

A patent is a legal title granting its proprietor the right to prevent third parties from commercially using an invention without authorisation. An invention is usually a **product** or a **process**.

The term of the patent is limited.

Like other forms of intellectual property, the rights provided by a patent do not actually permit their owner to do anything. But they do enable him to stop other people doing things: they enable him to exclude others from practising the invention within the state in which they were granted.

Product

An object, chemical or device; i.e. a physical thing

Process

A method of making or doing something; a recipe

General considerations

Patents are granted after successful application to, and examination by, a patent office. This may be the national patent office of a state (e.g. the UK Intellectual Property Office, the *Deutsches Patent- und Markenamt* (Germany) or the *Institut national de la propriété industrielle* (France)). For those states that contract to the European Patent Convention (EPC), it may also be the European Patent Office (EPO) in Munich.

Further information

www.epo.org/

Patents are currently domestic in nature. There is at present no such thing as a transnational patent. Even though applications for protection in multiple states may be made to the EPO, these become a bundle of national patents upon grant. Accordingly, the EPO has no jurisdiction to consider issues of patent infringement. That is left to the national courts.

There are currently 38 contracting states to the EPC, each having domestic patent legislation which in its essentials follows the corresponding provisions of the EPC.

Patentability

In order to gain patent protection, an invention must satisfy five fundamental requirements:

- (1) There must in fact be an invention.
- (2) The invention must be new.
- (3) It must possess a degree of inventiveness over what has gone before (i.e. it must involve what is known as an inventive step).
- (4) It must be susceptible of industrial application.
- (5) It must not fall within a list of “excluded” subject-matter.

These fundamental requirements are set out in **Article 52 EPC** and are replicated in the national laws of the EPO’s member states.

A patent has a maximum term of 20 years from the date of filing of the patent application in the state in question. For it to stay in force for this term, regular renewal fees must be paid. Failure to pay the renewal fees may cause the patent or patent application to lapse.

Article 52 EPC

Patentable Inventions

(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.

Introducing infringement

A patent gives its owner the exclusive right to prevent third parties that do not have the patent holder’s consent from performing certain acts with the patented invention within the territory in question.

The restricted acts are derived from what is now **Article 25 of the 1989 Draft Community Patent Convention (CPC)**. The CPC never came into force, but at the time that the original EPO member states were re-drafting their national laws to bring them into line with the EPC, it looked as though it would. Accordingly, the states based their primary infringement provisions upon it. The restricted acts include making, selling and using as well as importing or stocking for these purposes. Secondary infringement is also possible.

As already mentioned, at present there is no such thing as a transnational patent. If an individual or company wants their invention to be protected in different states, they must ensure that they hold rights in each of those states. Producing the invention of a German patent in France (for example), or selling allegedly infringing products there, does not constitute infringement. It would, however, be an infringement to import infringing products made in France into Germany.

Article 25 of the 1989 Draft CPC

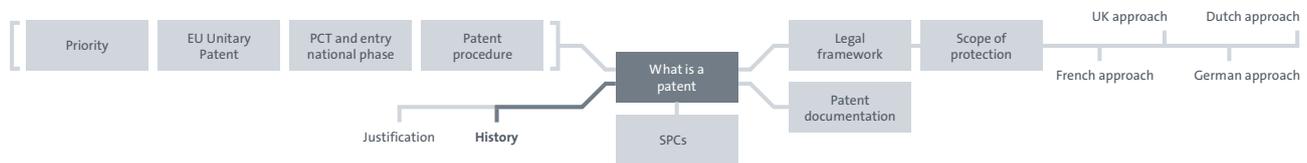
Prohibition of direct use of the invention
A Community patent shall confer on its proprietor the right to prevent all third parties not having his consent:

(a) from making, offering, putting on the market or using a product which is the subject-matter of the patent, or importing or stocking the product for these purposes;

(b) from using a process which is the subject-matter of the patent or, when the third party knows, or it is obvious in the circumstances, that the use of the process is prohibited without the consent of the proprietor of the patent, from offering the process for use within the territories of the Contracting States;

(c) from offering, putting on the market, using, or importing or stocking for these purposes the product obtained directly by a process which is the subject-matter of the patent.

A brief history (Supplementary reading)



The patent system as we know it today is a relatively modern innovation. The idea of a patent office employing a corps of examiners to ensure that applications comply with the requirements for patentability was pioneered in the United States with the passage of the Patents Act of 1836. In the UK, substantive examination only came about with the Patents Act of 1902.

Nevertheless, the idea of the use of monopoly privilege as an incentive to create or as a reward for creation is very old indeed. One of the earliest examples of this practice is found in the Greek city of Sybaris some 500 years BC. Sybaris was renowned for the luxurious lifestyle of its citizens, and the Sybarites are documented as having passed a law enabling the creator of a unique and excellent culinary dish to claim monopoly over that dish for one year, and to thereby reap all profit from its manufacture for this period. The intention appears to have been to induce confectioners and cooks to labour to excel.

The first systematic use of monopoly that can lay claim to being a precursor to modern patent law is found in Venice in the late 15th century.

The **Statute of Venice of 1474** demonstrates a modern approach to the protection of inventions. The preamble to the Statute declared that its intention was to provide protection so that “more men would then apply their genius [to create...] devices of great utility and benefit to our commonwealth.” In other words, protection was provided in order to induce innovation, a principle that underpins the patent laws of all major states today.

The Statute contained all the essential features of modern patent laws. It stated that devices must be novel (new and ingenious, not previously made in the Commonwealth) and reduced to perfection. It laid down a term of protection (10 years), provided for the licensing of the invention, and set out a procedure for determining infringement, to provide a remedy in damages and calling for destruction of the infringing article.

While the direct influence of the Statute of Venice is hard to gauge, the utility of the offer of monopoly as an incentive to or reward for inventive

The Statute of Venice of 1474

“We have among us men of great genius, apt to invent and discover ingenious devices; and in view of the grandeur and virtue of our city, more such men come to us every day from divers parts. Now, if provision were made for the works and devices discovered by such persons, so that others who may see them could not build them and take the inventor’s honour away, more men would then apply their genius, would discover, and would build devices of great utility and benefit to our commonwealth”.

effort is undeniable. By the mid-1500s the practice had found firm footing in England too.

When Elizabeth I came to the throne in 1558, England was not only poor (Elizabeth's father's excesses and petty wars having seen to that), it was also technologically backward compared with the rest of Europe. The early years of Elizabeth's reign are marked by the conscious acceleration of a policy to stimulate domestic industry in order that the technologically backward state might become self-sufficient. Central to this was the acquisition of superior technology, particularly in those areas that had featured most prominently on the list of imports.

While invention in the modern sense was not excluded from protection, the Queen's main target was foreign artisans. Foreign workers were therefore given monopolies in return for introducing new technologies and manufactures and teaching these to the native populace.

Elizabeth's policy was a great success. At the start of her reign there was a desperate need for ordnance, but by the end, English cannon were considered to be amongst the best in Europe, and even the Spanish tried to buy them.

There was, however, a dark side to this monopoly policy. The Queen was quick to realise that it could be used to reward favourites without emptying the royal purse. Courtiers soon held monopolies in established industries, including the production of salt, vinegar and starch. Prices rose and quality fell. Eventually, things came to a head, with Parliament threatening to intervene. In response, the Queen opened up her grants to judgment by the courts, and in 1602 in the case of **Darcy v Allen** the court of common law ultimately declared monopoly to be against the ancient and fundamental laws of the land, unless it was for a manner of new manufacture.

This principle was placed onto statutory footing some 20 years later in the Statute of Monopolies of 1624, which, in its Section 1, declared all monopolies void. However, Section 6 made an exception for patents relating to a new manner of manufacture for a limited term. This section formed the foundation for English patent law that was to last until the passage of the Patents Act 1977.

As part of the British Empire, the "newly discovered" North America inherited English law on monopolies. It was transported to the dependency with the first settlers, where it evolved into a patent custom initially little changed from its roots.

Nevertheless, following Independence and the Civil War, the newly formed United States of America soon took matters into their own hands

Odious monopoly & the Statute of Monopolies

"Where a man by his own charge and industry, or by his own wit or invention doth bring any new trade into the Realm, or any engine tending to the furtherance of a trade that never was used before: and that for the good of the Realm: that in such cases the king may grant him a monopoly patent for some reasonable time, until such subjects may learn the same, in consideration of the good that he doth bring by his invention to the commonwealth: otherwise not".

Statement of counsel for the defendant in *Darcy v Allen* (1602) 11 Co Rep 84b

Darcy v Allen

The case concerned a monopoly for the manufacture, importation and sale of playing cards, which by the time of the case were certainly not a new invention. The grant was first made in 1576, was reissued twice and finally came into Lord Darcy's hands in 1598. By the beginning of the 17th century it was wholeheartedly infringed. Whilst the decision is, in one respect, a simple issue of infringement, it must be seen against a wider background of the constitutional struggle between Parliament and the Crown for supremacy. Parliament eventually won, and the case was instrumental in this process

and made a clear statement of intent by making patent protection a constitutional right of US citizens. Thereafter, in the very early days of the first Congress, a nationwide patent system was created by legislative power.

Whilst initial patents acts were crude by modern-day standards, the Act of 1836 was probably the first in the world to adopt a genuinely modern approach to the protection of inventions. It instituted a formal system of examination and made the inclusion of patent claims a **statutory requirement**.

The mid-to-late 19th century was a time of great uncertainty as far as patents were concerned. Bureaucratic and administrative inefficiencies, combined with extraordinary expense and uncertainties in enforcing protection, had led many to question the validity of a patent system at all. There was also a growing trend at this time to criticise the system on more philosophical grounds. Many claimed that patents did little to improve technology; others said that they simply placed barriers in the way of those that wanted to innovate in any given area. Critics of the English system pointed to Germany's industrial progress (Germany had no patent law until 1877), arguing that this was clear evidence that the patent system was not needed to encourage innovation.

Notwithstanding some notable successes (The Netherlands, for example, adopted its first patent law in 1817, but then abolished it in 1869 at the height of the controversy), the abolitionists eventually lost the day. Fundamentally, therefore, the "patent controversy" demonstrated that patents were justifiable, even if the system could benefit from reform.

By the end of the 19th century, patents were becoming an international concern. International trade was on the increase and it was no longer possible to consider patents (or indeed any other industrial property, including designs and trade marks) at a purely domestic level.

Accordingly, in 1873 a Congress was held in Vienna that debated a number of international issues connected with the protection of inventions. Ultimately, this Congress paved the way for the grandfather of international industrial property treaties, the Paris Convention of 1883.

The Paris Convention followed on from three conferences, held in 1878, 1880 and 1883, which debated provisions that, it was hoped, would overcome the worst difficulties facing patentees with international interests, and would at the same time be politically practical. The resultant text of the Convention provided for new concepts such as "**national treatment**" and "**Convention priority**" that still play a major part in patent law today.

The US Constitution & early Patents Acts

"Congress shall have power... To promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries."

Article 1, §8, cl8 of the Constitution of the United States of America

Statutory requirement for the claims

Section 6 of the 1836 Act introduced a requirement that the potential patentee 'particularly specify and point out the part, improvement, or combination, which he claims as his own invention or discovery'. Prior to this point, all that had been required was a simple description of the invention so as to distinguish it from things already known and used.

National treatment

The requirement that a Convention country must treat applications from nationals of other Convention countries as it would its own. This is found in Article 2 Paris Convention.

Convention priority

The idea that a first application for a patent in one member state will not prejudice a later application in another member state as long as it is within the prescribed period. The prescribed period for patents is 12 months. (Article 4 of the Convention).

Modern developments

During the 20th century, the pressure for a more harmonised approach to the treatment of patents did not abate. Nevertheless, there were also some more immediate practical concerns. Foremost amongst these was the difficulty and impracticality of applying for the same patent in different countries. Although the Paris Convention created the notion of Convention priority, the actual process of making multiple applications was still cumbersome.

Agreed in Washington in 1970, the Patent Cooperation Treaty created a procedural mechanism to assist prospective patentees wishing to obtain protection in more than one state. Under the PCT, a single application can be made which is then subjected to an international search and **preliminary examination** before being turned into a bundle of national applications for designated countries.

Preliminary examination

An examination to check that the application is in order. This is not an examination of the patentability of the invention in question.

The European Patent Convention (EPC) is a multilateral treaty that created the European Patent Organisation and provides a system of centralised search, examination and grant at the European Patent Office (EPO). It provides a framework for the harmonisation of substantive law on patentability within the states that contract to it. The text of the EPC therefore forms the basis for the criteria of patentability that can be found in the domestic legislation of its member states.

The original text of the EPC was amended in November 2000 at a Diplomatic Convention held in Munich. The amendments came into force in December 2007.

There are currently **38 member states** of the European Patent Organisation, and a further two **extension states**.

38 member states of the European Patent Organisation

Austria, Belgium, Bulgaria, Switzerland, Cyprus, Czech Republic, Germany, Denmark, Estonia, Spain, Finland, France, United Kingdom, Greece, Croatia, Hungary, Ireland, Iceland, Italy, Liechtenstein, Lithuania, Luxembourg, Latvia, Monaco, Former Yugoslav Republic of Macedonia, Malta, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Sweden, Slovenia, Slovakia, San Marino and Turkey.

The EPC (and also the EPO) does not concern itself with issues of enforcement and infringement of patents: these are purely national concerns.

Extension states

States recognising European patents upon request: Bosnia and Herzegovina, and Montenegro

Patents granted under the EPC are referred to as “European patents”, but they are not unitary in character. Once granted, these patents enter what is known as the “national stage” and become enforceable as if they were purely domestic applications.

Infringement and revocation actions are therefore heard by local (i.e. national) courts in the member states in question. (For the effect of a “European” patent in the UK, see **Sections 77 to 83 Patents Act 1977**.)

There are, however, two centrally administered procedures that can occur after grant and which can affect all patents in the national stage. These are the **opposition** and **limitation or revocation** procedures.

At the same time that the Council of Europe was debating what was to become the European Patent Convention, the European Community (as was) was finalising what it hoped would become the sister convention to the EPC, providing unitary patent protection for the member states of the EEC: the Community Patent Convention (CPC). The CPC was intended to build upon the EPC and to deal with aspects of infringement and revocation.

The contracting parties expected the CPC to enter into force, so when amending their national laws on patentability to bring these into line with the EPC, they also amended their provisions on infringement to harmonise with the CPC. Ultimately, the CPC did not enter into force, despite renewed attempts in the 1980s to get it to do so. But nevertheless, the infringement provisions of the UK, Germany and France (amongst many others) are modelled upon it (provisions relating to direct infringement are found in Article 25 of the 1989 Draft CPC; Article 26 deals with indirect infringement).

More recently, attempts have been made to further the harmonisation of intellectual property laws on a worldwide basis. Accordingly, the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), administered by the World Trade Organization, sets out certain minimum standards for many forms of IP rights.

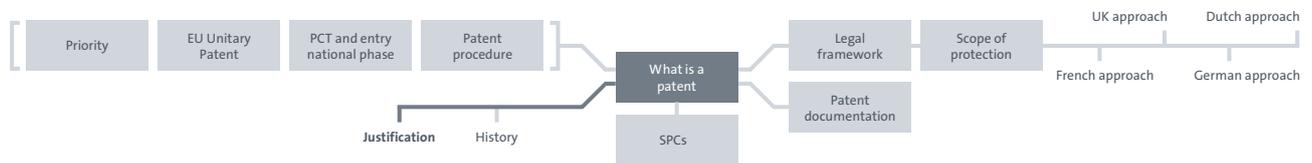
The TRIPS agreement requires members of the WTO to adhere to fairly strict intellectual property standards, in many cases going far beyond those demanded under previous international conventions. In the field of patents, TRIPS states (under Article 27) that patents must “be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application”. Article 52 EPC mirrors this provision closely.

Section 77(1) Patents Act 1977

“Subject to the provisions of this Act, a European patent (UK) shall, as from the publication of the mention of its grant in the European Patent Bulletin, be treated for the purposes of Parts I and III of this Act as if it were a patent under this Act granted in pursuance of an application made under this Act and as if notice of the grant of the patent had, on the date of that publication, been published under section 24 above in the journal; and -

- (a) the proprietor of a European patent (UK) shall accordingly as respects the United Kingdom have the same rights and remedies, subject to the same conditions, as the proprietor of a patent under this Act...;”

Justification for the patent system (Supplementary reading)

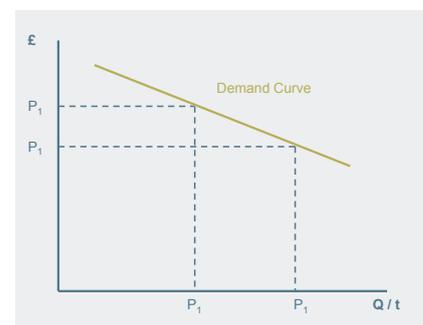


Basic economic considerations

Basically speaking, patents are concerned with information. They contain instructions on how to make, perform or operate a product or process. Information is essentially a free good which cannot be exhausted by use; many people can use the same piece of information at the same time to no ill effect. However, it is also a public good, meaning that, barring some sort of legal intervention, it is not exclusive once disclosed. This causes problems.

In the absence of some sort of protection, once an invention has been disclosed it is freely appropriable and therefore of strictly limited worth to its creator. It is, of course, worth an amount commensurate with its market value. But if copied without recompense to the inventor, this value will drop as competition will push the price down.

By giving patentees an exclusive right over their inventions, patents provide a way of dealing with the problems of the free and public nature of information. However, such exclusive rights are not always seen as beneficial. Like other forms of intellectual property, patents stop people doing things. So there may be a need to provide a justification of the patent system.



Theories of protection

The natural rights thesis is a moral justification based upon the assertion that the individual has a natural property right in his ideas. By extension, creators also have a natural right to the sole exploitation of these ideas, such that unauthorised use by others without compensation must be condemned as theft. This property is exclusive and personal, and therefore society (and also the state) is under a moral obligation to recognise and protect these rights.

The natural rights argument found firm footing in the French Patent Law of 1791, which explicitly recognised the principle in its preamble.

Nevertheless, it is not a theory that finds much support in modern literature. Critics note that if property in ideas is a natural right, there is little logical basis for that right to be limited to a term of years; rather it should be perpetual. In addition, it does not sit comfortably with any requirement of registration or criteria for patentability that the inventor must satisfy before this “property” is acknowledged. Moreover, the natural rights approach would not justify the provision of an exclusive right where both copying and independent creation are similarly prohibited.

More promising, perhaps, as a justification of the patent right is the idea that it is a reward for the efforts of the inventor. Protection is justified in the name of fairness, to secure for the inventor his just reward, proportional to the usefulness of the invention to society. As this reward cannot be guaranteed by reliance upon ordinary market forces, state intervention is justified in the provision of a temporary right.

Nevertheless, despite being based on solid utilitarian thinking, the reward theory is not without its problems. First, if inventors are being rewarded, what are they actually being rewarded for? What is the rationale for being given exclusive privilege? If the patent is granted for their labour, this returns us to the natural rights of the author, which is not a concept that many take too seriously. If the patentee is rewarded for having a good idea, this moves us to ask why it is only the first one to take the invention to the patent office who receives the reward. What is there in the nature of invention that makes independent re-creation less worthy than the initial creation?

More persuasive as a justification of the patent system are the arguments that it provides necessary incentives to invent, to invest in the process of invention and to disclose the fruits thereof. The incentive theories are primarily economic in nature, and are therefore independent of the question of whether justice calls for inventors to be rewarded for their efforts.

The apparent nexus between the patent system and economic development, which paints patents as a lever of industrial progress, has enchanted proponents of the system since the theory was first advanced, and has undoubtedly been a factor in incentive theory becoming probably the most quoted argument in favour of patents.

When used as an explanation of the beneficial effects of patents, the theory balances upon a number of assumptions: First, that growth and industrial progress are socially desirable. Second, that invention is necessary for this progress. Third, that the level of invention/innovation or disclosure will be sub-optimal without incentives. Finally, that patents are the cheapest and most effective way in which these incentives can be provided.

Given the expense of modern research and development, especially in fields such as pharmaceuticals, it is easy to see why the incentive theory is predominant in the justification of patents. Without the sort of protection offered by the patent system, no one would invest in the process of invention, as they would know that the end product could easily be copied by others who had not had to endure the same sunken costs of development. Equally, no one would ever disclose a secret process for the same reason. Without protection, others could use it freely, thereby eroding any advantage the inventor had.

Nevertheless, it is clear that patents can block innovation as well as encourage it. Indeed, the whole point of the patent monopoly is to exclude others during the currency of its term. Therefore a price must be paid and society must be enriched in order for the patent to be justified. In modern patent law, the fundamental price that the patentee pays to society is that of disclosure – making their invention available for use by the relevant public by virtue of their written specification. In return, the patentee gets up to 20 years of exclusivity. After that, the public enjoys its legacy. This is often referred to as the “*quid pro quo*”.

A time-limited monopoly

Evidently, no matter which justification is used, it would be seriously undesirable to allow inventors to monopolise the technology that they have created forever. Giving inventors an exclusivity right allows them to restrict supply. Restricting supply allows the price to be raised. Raising the price means that the social utility of the invention is not maximised – as not all who could benefit from it are able to buy access to it. Accordingly, the patent term is limited to a maximum of 20 years. This is considered to be sufficient time for patentees to make enough profit from their invention to justify their initial investment. Usually it works – a large proportion of patents lapse long before their 20 years are up.

For some, however, 20 years is not enough. Products in certain fields, for example pharmaceuticals and certain agricultural chemicals, require regulatory approval before they can be marketed, and this eats into the 20 years of patent protection that they enjoy. Accordingly, there are **special provisions** covering **Supplementary Protection Certificates (SPCs)** which extend protection for these products for up to five years from the normal date of expiry of the patent.

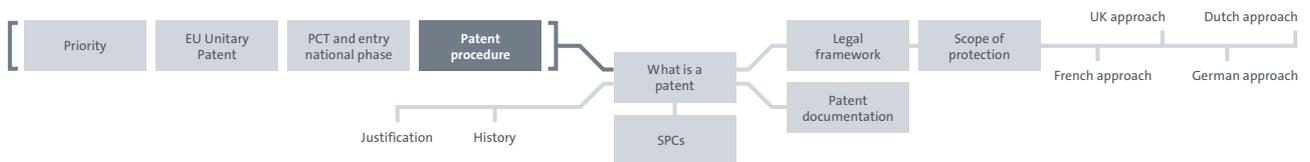
"No economist, on the basis of present knowledge, could possibly state with certainty that the patent system, as it now operates, confers a net benefit or a net loss upon society. ... If we did not have a patent system, it would be irresponsible, on the basis of our present knowledge of its economic consequences, to recommend instituting one. But since we have had a patent system for a long time, it would be irresponsible, on the basis of our current knowledge, to recommend abolishing it."
Machlup, An Economic Review of the Patent System, Study No. 15 of the Sub-Committee on Patents, Trademarks and Copyrights of the Committee on the Judiciary, US Senate 85th Congress, 2nd Session, (1958, Washington) at 80–1

Special provisions

Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products (Codified version), and Regulation (EC) No 1610/96 of the European Parliament and of the Council of 23 July 1996 concerning the creation of a supplementary protection certificate for plant protection products.

Patent procedure

Essentials: Procedure



The European Patent Office and the Administrative Council

The European Patent Organisation is an intergovernmental organisation set up in 1977 on the basis of the European Patent Convention (EPC).

It has two organs: the European Patent Office (EPO), which is the executive arm of the European Patent Organisation and the Administrative Council, which supervises the activities of the European Patent Office (Article 4 EPC).

The EPO's core activity is the examination of patent applications and the grant of European patents.

The EPO is also responsible for:

- Examining oppositions filed against granted European patents.
- Providing patent information and training services.

The European Patent Organisation currently has **38 member states (Contracting states)**. There are a further **two extension states and four validation states** recognising European patents upon request.

38 member states

Albania; Austria; Belgium; Bulgaria; Switzerland; Cyprus; Czech Republic; Germany; Denmark; Estonia; Spain; Finland; France; United Kingdom; Greece; Croatia; Hungary; Ireland; Iceland; Italy; Liechtenstein; Lithuania; Luxembourg; Latvia; Monaco; Former Yugoslav Republic of Macedonia; Malta; Netherlands; Norway; Poland; Portugal; Romania; Serbia; Sweden; Slovenia; Slovakia; San Marino; Turkey.

Two extension states

Bosnia and Herzegovina; Montenegro

The EPO's official languages

The EPO has three official languages: English, French and German.

Applications may be filed with the EPO in any language. However, according to **Article 14(2) EPC**, applications made in any language other than the EPO's official languages (i.e. English, French or German) must be translated into one of the official languages.

Article 14(2)(3)(6) EPC
Languages of the European Patent Office, European patent applications and other documents
→ see below

This must be done within two months of the initial filing. If the required translation is not filed in due time, the application will be deemed to have been withdrawn.

Article 14(2)(3)(6) EPC

Languages of the European Patent Office, European patent applications and other documents

(2) A European patent application shall be filed in one of the official languages or, if filed in any other language, translated into one of the official languages in accordance with the Implementing Regulations. Throughout the proceedings before the European Patent Office, such translation may be brought into conformity with the application as filed. If a required translation is not filed in due time, the application shall be deemed to be withdrawn.

(3) The official language of the European Patent Office in which the European patent application is filed or into which it is translated shall be used as the language of the proceedings in all proceedings before the European Patent Office, unless the Implementing Regulations provide otherwise.

(6) Specifications of European patents shall be published in the language of the proceedings and shall include a translation of the claims in the other two official languages of the European Patent Office.

Composition of the EPO

The procedures under the EPC are carried out by the following units of the European Patent Office:

- Receiving Section
- Search divisions
- Examining divisions
- Opposition divisions
- Legal Division
- Boards of Appeal
- Enlarged Board of Appeal

The Receiving Section is responsible for the preliminary examination of applications for patents, i.e. for ensuring that applications are complete and that the relevant fees have been paid (Article 16 EPC).

The search divisions are responsible for drawing up search reports, i.e. creating a list of the documents which shall be considered when deciding whether the invention to which a patent application relates is patentable (Article 17 EPC).

Examining divisions are responsible for the substantive examination of patent applications, i.e. determining whether the claimed invention is patentable or not (Article 18 EPC).

Opposition divisions are responsible for the examination of any oppositions against European patents.

The Legal Division is responsible for maintaining the Register of European Patents and the list of professional representatives (Article 20 EPC).

Boards of Appeal

The technical Boards of Appeal hear appeals against decisions of the Receiving Section and the examining and opposition divisions, whereas the Legal Board of Appeal hears appeals against decisions of the Legal Division.

The Boards of Appeal are independent of the Office in their decisions and are bound only by the EPC itself. The EPC safeguards the independence and impartiality of their members who shall not be bound by any instructions other than the provisions of the EPC (Art. 23(3) EPC). The members of the Boards of Appeal are appointed by the Administrative Council of the European Patent Organisation for a term of five years.

Decisions of the boards are made available via the European Patent Register and the EPO's Official Journal. A database of decisions is also available online.

Enlarged Board of Appeal

The Enlarged Board of Appeal ensures the uniform application of the law. If an important point of law arises, a question can be referred to the Enlarged Board of Appeal, either by a Board of Appeal or by the President of the Office.

The Enlarged Board of Appeal

The Enlarged Board of Appeal deals with cases referred to it either by one of the technical boards of appeal, by the Legal Board of Appeal or by the President of the European Patent Office. Cases are referred to the Enlarged Board for a decision on an important point of law or in order to secure uniform application of the law (Article 112 EPC).

The Enlarged Board also examines petitions for review of decisions of the Boards of Appeal under Article 112(a) EPC.

The choice of application route

There are a number of different routes to patent protection. The optimal route for any given invention will depend on the markets in which protection is desired.

The EPO accepts applications under the European Patent Convention (EPC) and the Patent Cooperation Treaty (PCT). Alternatively, applicants may choose to apply direct to the national offices of the states in which they desire protection. This latter route may prove to be financially worthwhile where the number of states in which protection is desired is small.

Filing an application under the European Patent Convention

Any natural or legal person may file a patent application (Article 58 EPC).

Applications may be filed by single or multiple applicants, and by different applicants either jointly or with each designating different contracting states (Article 59 EPC). Nevertheless, the right to be granted a European patent belongs primarily to the inventor or their successor in title. Where the inventor is an employee, the national law of the state in which the inventor is mainly employed will be used to determine ownership of the patent (Article 60 EPC).

In any case, the inventor has the right to be named as such before the European Patent Office (Article 62 EPC).

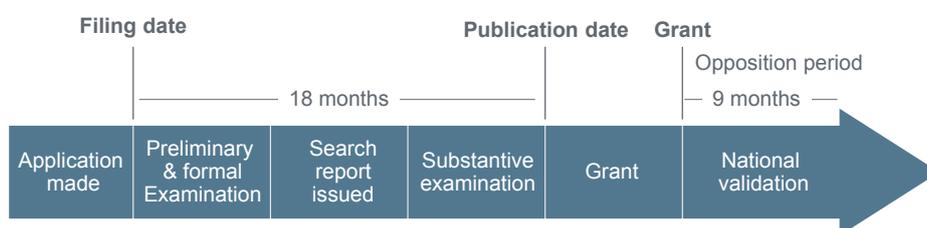
Designation

Applicants for a European patent “designate” the contracting states in which protection is desired.

When a European patent application is filed, all the contracting states are deemed to be designated by default.

However, these designations must subsequently be confirmed by payment of the appropriate fee. Accordingly, before this fee is paid, applicants may withdraw applications in states where protection is not required.

Application process



Significant dates and periods

There are a number of critically important dates or periods of time that have special significance in the European patent system. They include the priority date, the filing date, the date of publication, the date of grant and the opposition period.

The date of filing and date of priority

The date of filing is the date on which the application as received by the **Receiving Section** satisfies **certain requirements**.

It is the date from which the term of the patent is calculated (Article 63 EPC).

In certain cases applicants may claim an earlier priority date (up to 12 months earlier) of a **“Convention” application** for the same invention (Article 87 EPC), provided that they are also the applicants of the earlier application (or their successor in title).

In order to sustain a claim for priority, the application must be supported by matter disclosed in the earlier application. In practice, this means that the specific combination of features present in the claim must be at least implicitly disclosed in the previous application.

The filing date will represent the date at which the invention’s patentability (novelty, inventive step, etc.) is assessed.

Matter made available to the public before the application’s priority or filing date will be considered part of the prior art.

Receiving Section

The EPO has filing offices in Munich, The Hague and Berlin.

Certain requirements

Rule 40(1) EPC

The date of filing of a European patent application shall be the date on which the documents filed by the applicant contain:

- (a) an indication that a European patent is sought;
- (b) information identifying the applicant or allowing the applicant to be contacted; and
- (c) a description or reference to a previously filed application.

“Convention” application

An application in a Paris Convention state or a WTO member state.

Decision of the Enlarged Board of Appeal G 2/98

The patenting process under the EPC for European patents

Preliminary examination

When an application is received by the Receiving Section, the documents making up that application are first marked with the date of receipt and a receipt is issued to the applicant.

The EPO then examines the application to determine whether it meets the minimum requirements for according a filing date, i.e. that it contains:

- (i) an indication that a European patent is sought;
- (ii) information identifying the applicant or allowing the applicant to be contacted; and
- (iii) a description or reference to a single previous application.

Applicants do not actually have to provide any claims in order to obtain a date of filing. If an application is filed without claims, but satisfies all the requirements for obtaining a date of filing, the applicant will be requested to provide at least one claim later.

Formal examination

Once the application has been accorded a filing date, the Receiving Section then examines it to ensure that it meets a number of formal requirements. These requirements are set out in Article 90(3) EPC and relate to the following:

- (i) representation
- (ii) physical requirements of the application
- (iii) abstract
- (iv) request for grant
- (v) claim to priority
- (vi) designation of the inventor
- (vii) translations, where required
- (viii) the presence of at least one claim
- (ix) filing and search fees

The Receiving Section also checks the claims and description in order to ensure that the title of the invention is in general accord with **Rule 42 EPC**. It checks that any other relevant fees have been paid and that deposits of biological material have been made, or sequence listings provided for nucleotide and/or amino acid sequences, where appropriate.

Rule 42 EPC
Content of the description
→ see below

Rule 42 EPC

Content of the description

- (1) The description shall:
 - (a) specify the technical field to which the invention relates;
 - (b) indicate the background art which, as far as is known to the applicant, can be regarded as useful to understand the invention, draw up the European search report and examine the European patent application, and, preferably, cite the documents reflecting such art;
 - (c) disclose the invention, as claimed, in such terms that the technical problem, even if not expressly stated as such, and its solution can be understood, and state any advantageous effects of the invention with reference to the background art;
 - (d) briefly describe the figures in the drawings, if any;
 - (e) describe in detail at least one way of carrying out the invention claimed, using examples where appropriate and referring to the drawings, if any;
 - (f) indicate explicitly, when it is not obvious from the description or nature of the invention, the way in which the invention is industrially applicable.
- (2) The description shall be presented in the manner and order specified in paragraph 1, unless, owing to the nature of the invention, a different presentation would afford a better understanding or be more concise.

Search and publication

Search

The aim of the search is to discover the prior art which is relevant to determining whether (and if so to what extent) the claimed invention for which protection is sought is new and involves an inventive step.

Searches are made on the basis of the claims, with due regard to the description and drawings (if any) (**Article 92 EPC**).

A search report is prepared containing the results of the search, in particular identifying the documents constituting the relevant prior art.

A non-binding opinion on patentability is also issued.

Article 92 EPC

Drawing up of the European search report

The European Patent Office shall, in accordance with the Implementing Regulations, draw up and publish a European search report in respect of the European patent application on the basis of the claims, with due regard to the description and any drawings.

Publication

Applications are published as soon as possible after the expiry of a period of 18 months from the date of filing or, where priority is claimed, from the earliest priority date. They may, however, be published before this if requested by the applicant and provided that the relevant fees have been paid (**Article 93(1) EPC**).

If the application is withdrawn before this date, its contents do not become part of the state of the art.

The publication must contain the description, the claims and any drawings as filed, including any late-filed missing parts of the description or missing drawings (Rule 56 EPC). It must also specify, where possible, the names of the person or persons designated as the inventor(s).

Article 93(1) EPC

Publication of the European patent application

(1) The European Patent Office shall publish the European patent application as soon as possible

(a) after the expiry of a period of eighteen months from the date of filing or, if priority has been claimed, from the date of priority, or

(b) at the request of the applicant, before the expiry of that period.

Following publication

Provisional protection in all states designated is obtained upon publication. Applicants may therefore claim reasonable compensation from third parties who infringe their patent applications after this point, provided that the application eventually proceeds to grant. However, the patent does not convey any rights to enforce the patentee's monopoly until the date of grant. In effect, it means that in an action for infringement, claims for compensation can be backdated to the publication date.

In order to take the application further once it has been published, various fees must be paid. These include an examination fee and a designation fee (as well as an extension fee (if applicable)).

After publication of the application, third parties may present observations on the patentability of the invention to which it or the patent relates, as long as proceedings are pending before the EPO. These observations may be filed online and are free of charge.

Substantive examination

Following a **request for examination** and payment of the appropriate fee, the application is transferred to the examining division, where it is subjected to substantive examination. If no request for examination is made within six months of publication, the application is deemed to be withdrawn.

Substantive examination considers the patentability of the application, i.e. whether the invention is new, involves an inventive step, is capable of industrial application and does not fall within excluded subject-matter and some other requirements, such as whether the invention as disclosed in the application can be reproduced, the clarity of the claims, or whether any amendments go beyond the disclosure of the application as originally filed.

If the examination reveals that the application or the invention to which it relates does not meet the requirements of the EPC, the examining division will raise the appropriate objections. The applicant may provide counter-arguments and/or amendments to try and overcome these objections. If all objections are overcome, a patent will be granted. Otherwise the application will be refused.

Request for examination

The request for examination may be filed by the applicant up to the end of six months after the date on which the European Patent Bulletin mentions the publication of the European search report.

Article 123(1) EPC Amendments

(1) The European patent application or European patent may be amended in proceedings before the European Patent Office, in accordance with the Implementing Regulations. In any event, the applicant shall be given at least one opportunity to amend the application of his own volition.

Pre-grant amendment

Applicants may amend their applications before the patent is granted with relative ease (although for European patents filed directly at the EPO (not via the PCT) they may only be amended once the European search report has been received – see Rule 137(1) EPC).

Under Article 123(1) EPC applicants must be given at least one opportunity to amend the application of their own volition. Applications may also be amended in response to the search opinion (**Rule 137(2) EPC**) or to objections raised during examination (see Rule 71(1) EPC and Article 94(3) EPC).

Applicants may correct **obvious errors** at any time (Rule 139 EPC).

In all cases, the amendments made must satisfy the following conditions:

- (i) They must not add subject-matter to the content of the application as filed (Article 123(2) EPC).
- (ii) They must not themselves cause the application as amended to be objectionable under the EPC, e.g. they must not introduce a lack of clarity into the claims (Article 84 EPC).

Rule 137(2) EPC

Amendment of the European patent application

(2) Together with any comments, corrections or amendments made in response to communications by the European Patent Office under Rule 70a, paragraph 1 or 2, or Rule 161, paragraph 1, the applicant may amend the description, claims and drawings of his own volition.

Obvious errors

Obvious errors include linguistic errors and errors of transcription as well as other mistakes in documents filed with the EPO. Where the mistake is in the description, claims or drawings, both the error and the correction must be such that it is immediately evident (at least once attention is directed to the matter) that both (a) an error has occurred; and (b) what the correction should be. Both requirements are viewed through the eyes of the person skilled in the art.

- (iii) They must comply with Rule 137(5) EPC in that the amended claims may not relate to unsearched subject-matter which does not combine with the originally claimed invention or group of inventions to form a single general inventive concept.

Grant

If the examining division has decided that a patent can be granted, it must inform the applicant of the text (i.e. specification (including claims)) on the basis of which it intends to grant it.

The text is communicated to the applicant along with an invitation to pay a fee for grant and publishing and a request that they file a translation of the claims into the two official languages of the EPO other than the language of the proceedings. An additional fee is also payable for each claim over and above 15 that is contained in the application.

The decision to grant

Once the requirements are satisfied, the decision to grant the patent will be issued. The decision to grant contains the date of the mention of the grant of the European patent and is sent to the applicant when the technical preparations for printing the patent specification have been completed. As soon as possible after the mention of the grant is published in the Bulletin, the EPO publishes the patent specification containing the description, claims (in the three official languages) and any drawings.

Grant and validation

The grant does not take effect until the date on which it is mentioned in the European Patent Bulletin.

The granted European patent is a “bundle” of individual national patents. In many contracting states, for the patent to retain its protective effect and be enforceable against infringers, it must undergo a further process of validation once it has been granted by the EPO. This means that, where necessary, the patent owner has to file with the national patent office concerned a translation of the specification, or at least of the claims, into an official language of the state concerned. Fees may also be payable by a certain date. These matters are governed by national law.

Opposition

After the European patent has been granted, it may be opposed by third parties – usually, but not necessarily, the applicant’s competitors – if they believe that it should not have been granted (for example, because the invention lacks novelty or does not involve an inventive step).

Oppositions are objections raised by third parties to the grant of a European patent. They must be filed within nine months of the mention of the grant of the patent in the European Patent Bulletin.

The examination of oppositions is handled by the opposition division.

If the opposition is successful, the patent is invalidated at source. If the opposition period has passed and the European patent has entered the national phase, anyone wishing to invalidate the patent will have to bring separate revocation actions in all the states in which the patent has effect (Article 19 EPC).

Renewal

The maximum life of a patent is 20 years from the date of filing. However, for it to remain effective, regular renewal fees must be paid. European patent applications are subject to renewal fees in respect of the third and each subsequent year, calculated from the date of filing (see **Article 86(1) EPC**).

Renewal fees in respect of the coming year are due on the last day of the month in which the anniversary of the date of filing falls. Fees increase year on year until year 10, after which they remain at the same level.

After mention of the grant, renewal is governed by national law.

Payment may still be validly made up to six months after the due date for a renewal fee, provided that an additional fee equal to 50% of the renewal fee is paid within the same period.

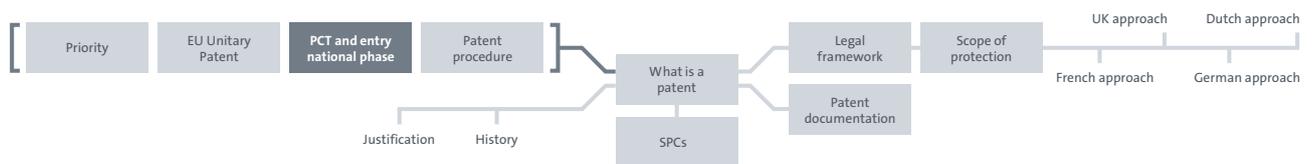
Article 86(1) EPC

Renewal fees for the European patent application

(1) Renewal fees for the European patent application shall be paid to the European Patent Office in accordance with the Implementing Regulations. These fees shall be due in respect of the third year and each subsequent year, calculated from the date of filing of the application. If a renewal fee is not paid in due time, the application shall be deemed to be withdrawn.

The PCT and entry into the national phase

Essentials: The PCT



The Patent Cooperation Treaty

The Patent Cooperation Treaty (PCT) was signed in Washington DC on 19 June 1970. It entered into force on 24 January 1978 and became operational when the first international application was filed on 1 June 1978.

Article 1(1) PCT: “The States party to this Treaty [...] constitute a **Union for cooperation** in the **filing, searching, and examination, of applications for the protection of inventions**, and for rendering special technical services.”

The PCT makes it possible to file international patent applications in accordance with a single procedure.

It does not provide for the grant of “international patents”. The patent offices of the contracting states for which protection is sought remain in charge of granting regional or national patents in the light of the results produced according to the PCT filing procedure.

PCT

www.wipo.int/export/sites/www/pct/en/texts/pdf/pct.pdf

PCT contracting states

www.wipo.int/pct/en/pct_contracting_states.html

WIPO website

www.wipo.int/pct/en/

Preliminary examination

The preliminary examination provides an optional, non-binding opinion on whether the claimed invention appears to be novel, to involve an inventive step and to be industrially applicable as defined in Article 33 PCT.

Relationship to Paris Convention

The PCT is a “special agreement” according to Article 19 of the Paris Convention:

Article 19 Paris Convention Special Agreements

It is understood that the countries of the Union reserve the right to make separately between themselves special agreements for the protection of industrial property, in so far as these agreements do not contravene the provisions of this Convention.

Hence, only member states of the Paris Convention may be contracting states to the PCT.

How it works

The PCT system is composed of two main phases: a single, international phase, followed by one or more national phases.

The international phase consists of up to five stages:

- The filing of the international application with, and its processing by, the receiving Office.
- The establishment of an international search report by an International Searching Authority.
- The publication of the international application by the International Bureau of WIPO.
- The (optional) establishment of a supplementary international search report by an authority specified for supplementary international search.
- The (optional) establishment of a preliminary examination report by an International Preliminary Examining Authority.

The national phase starts, upon completion of the international phase, if the applicant decides to continue processing the application before the regional or national patent offices with the aim of obtaining regional or national protection.

Article 2 PCT

Definitions

For the purposes of this Treaty and the Regulations and unless expressly stated otherwise:

(i) “application” means an application for the protection of an invention; references to an “application” shall be construed as references to applications for patents for inventions, inventors’ certificates, utility certificates, utility models, patents or certificates of addition, inventors’ certificates of addition, and utility certificates of addition;

(ii) references to a “patent” shall be construed as references to patents for inventions, inventors’ certificates, utility certificates, utility models, patents or certificates of addition, inventors’ certificates of addition, and utility certificates of addition;

(iii) “national patent” means a patent granted by a national authority;

(iv) “regional patent” means a patent granted by a national or an intergovernmental authority having the power to grant patents effective in more than one State;

(v) “regional application” means an application for a regional patent;

(vi) references to a “national application” shall be construed as references to applications for national patents and regional patents, other than applications filed under this Treaty;

[...]

Applying for a patent under the PCT

Any resident or national of a PCT contracting state may file an international application.

International applications have to be filed with a competent receiving Office. The applicant can choose from:

- The **national office** of the PCT contracting state of which the applicant is a resident or national, or with the office acting for that state.
- The **International Bureau** of the World Intellectual Property Organization (**WIPO**), irrespective of the PCT contracting state of which the applicant is a resident or national.
- The competent regional office, e.g. the **European Patent Office (EPO)** (provided that at least one applicant is a national or resident of a contracting state to the European Patent Convention (EPC)).

Article 9 PCT The applicant

- (1) Any resident or national of a Contracting State may file an international application.
- (2) The Assembly may decide to allow the residents and the nationals of any country party to the Paris Convention for the Protection of Industrial Property which is not party to this Treaty to file international applications.
- (3) The concepts of residence and nationality, and the application of those concepts in cases where there are several applicants or where the applicants are not the same for all the designated States, are defined in the Regulations.

Article 9 PCT
The applicant
→ see below

Receiving Office Article 2 PCT Definitions

For the purposes of this Treaty and the Regulations and unless expressly stated otherwise:

(xv) “receiving Office” means the national Office or the intergovernmental organization with which the international application has been filed;

EPO member states

www.epo.org/about-us/organisation/member-states.html

When the EPO acts as receiving Office it processes the application in accordance with the relevant provisions of the PCT. The provisions of the PCT and its Regulations are supplemented by the provisions of the EPC.

What are the elements of an international application?

International applications must contain the following elements:

- PCT request (Article 4 PCT)
- Description (Article 5 PCT)
- Claim(s) (Article 6 PCT)
- Drawing(s) (where required) (Article 7 PCT)
- Abstract (Article 3(3) PCT).

Article 3 PCT

The international application

[...]

(2) An international application shall contain, as specified in this Treaty and the Regulations, a request, a description, one or more claims, one or more drawings (where required), and an abstract.

[...]

The PCT request

PCT requests must contain:

- A petition to the effect that the international application is to be processed according to the PCT.
- The designation of the contracting state(s) in which protection is sought, indicating if national or, where available, regional patents are desired.
- The name of, and other prescribed data concerning, the applicant and the agent (if any).
- The title of the invention.
- The name of, and other prescribed data concerning, the inventor according to the legal requirements of the designated states.

Article 4 PCT
The request
→ see below

Article 4 PCT The request

(1) The request shall contain:

- (i) a petition to the effect that the international application be processed according to this Treaty;
- (ii) the designation of the Contracting State or States in which protection for the invention is desired on the basis of the international application ("designated States"); if for any designated State a regional patent is available and the applicant wishes to obtain a regional patent rather than a national patent, the request shall so indicate; if, under a treaty concerning a regional patent, the applicant cannot limit his application to certain of the States party to that treaty, designation of one of those States and the indication of the wish to obtain the regional patent shall be treated as designation of all the States party to that treaty; if, under the national law of the designated State, the designation of that State has the effect of an application for a regional patent, the designation of the said State shall be treated as an indication of the wish to obtain the regional patent; [...]

Description, claims and abstract

Article 5 PCT (The description): "The description shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art."

Article 6 PCT (The claims): "The claim or claims shall define the matter for which protection is sought. Claims shall be clear and concise. They shall be fully supported by the description."

Article 3(3) PCT: "The abstract merely serves the purpose of technical information and cannot be taken into account for any other purpose, particularly not for the purpose of interpreting the scope of the protection sought."

Drawings are only required "when they are necessary for the understanding of the invention" (**Article 7(1) PCT**).

Article 7 PCT The drawings

(1) Subject to the provisions of paragraph (2)(ii), drawings shall be required when they are necessary for the understanding of the invention.

(2) Where, without being necessary for the understanding of the invention, the nature of the invention admits of illustration by drawings:

- (i) the applicant may include such drawings in the international application when filed,
- (ii) any designated Office may require that the applicant file such drawings with it within the prescribed time limit.

The international filing date

The international filing date of an international application is the date of receipt of the application by the receiving Office, provided that the requirements in **Article 11(1) PCT** are fulfilled. These requirements are as follows:

- (i) The applicant does not obviously lack, for reasons of residence or nationality, the right to file an international application with the receiving Office.
- (ii) The international application is in the prescribed language.
- (iii) The international application contains at least the following elements:
 - (a) an indication that it is intended as an international application,
 - (b) the designation of at least one contracting state,
 - (c) the name of the applicant, as prescribed,
 - (d) a part which on the face of it appears to be a description,
 - (e) a part which on the face of it appears to be a claim or claims.

The international filing date of an application filed with the EPO as receiving Office is the date on which the application is received at one of the EPO's filing offices or, in exceptional cases, at a national patent office of an EPC contracting state acting as filing office on behalf of the EPO.

The term "international filing date" refers simply to the fact that the application concerned was filed as an application under the PCT.

The international search

For each international application, an international search is carried out by an **International Searching Authority** (ISA, e.g. the EPO), resulting in an **international search report** (ISR) and a **written opinion** (WO).

The objective of the international search is to discover relevant prior art.

The **international search report** contains (among other things):

- The citations of the prior art documents considered relevant.
- The classification of the subject-matter of the invention.
- The identification of the fields searched.

The international search report is published by the International Bureau of WIPO (**Article 21(3) PCT**).

Article 15 PCT

The international search

(1) Each international application shall be the subject of international search.

(2) The objective of the international search is to discover relevant prior art.

(3) International search shall be made on the basis of the claims, with due regard to the description and the drawings (if any).

[...]

Article 16 PCT

The International Searching Authority

→ see below

Article 21 PCT

International publication

[...]

(3) The international search report or the declaration referred to in Article 17(2)(a) shall be published as prescribed in the Regulations.

[...]

Article 16 PCT

The International Searching Authority

- (1) International search shall be carried out by an International Searching Authority, which may be either a national Office or an intergovernmental organization, such as the International Patent Institute, whose tasks include the establishing of documentary search reports on prior art with respect to inventions which are the subject of applications.
- (2) If, pending the establishment of a single International Searching Authority, there are several International Searching Authorities, each receiving Office shall, in accordance with the provisions of the applicable agreement referred to in paragraph (3)(b), specify the International Searching Authority or Authorities competent for the searching of international applications filed with such Office. [...]

The written opinion of the ISA

The **written opinion of the International Searching Authority** provides the applicant with a preliminary, non-binding opinion on the question of whether the claimed invention appears to:

- be novel
- involve an inventive step and
- be industrially applicable.

It allows the applicant to assess, at an early stage, whether to proceed to the national/regional phase.

Rule 43bis PCT

Written Opinion of the International Searching Authority

→ see below

Rule 43bis PCT

Written Opinion of the International Searching Authority

43bis.1 Written Opinion

- (a) Subject to Rule 69.1(b-bis), the International Searching Authority shall, at the same time as it establishes the international search report or the declaration referred to in Article 17(2)(a), establish a written opinion as to:
 - (i) whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), and to be industrially applicable;
 - (ii) whether the international application complies with the requirements of the Treaty and these Regulations in so far as checked by the International Searching Authority.The written opinion shall also be accompanied by such other observations as these Regulations provide for.
- (b) For the purposes of establishing the written opinion, Articles 33(2) to (6), 35(2) and (3) and Rules 43.4, 43.6bis, 64, 65, 66.1(e), 66.7, 67, 70.2(b) and (d), 70.3, 70.4(ii), 70.5(a), 70.6 to 70.10, 70.12, 70.14 and 70.15(a) shall apply mutatis mutandis.
- (c) The written opinion shall contain a notification informing the applicant that, if a demand for international preliminary examination is made, the written opinion shall, under Rule 66.1bis(a) but subject to Rule 66.1bis(b), be considered to be a written opinion of the International Preliminary Examining Authority for the purposes of Rule 66.2(a), in which case the applicant is invited to submit to that Authority, before the expiration of the time limit under Rule 54bis.1(a), a written reply together, where appropriate, with amendments.

The supplementary international search

Rule 45bis PCT
Supplementary International Searches
→ see below

Upon request by the applicant, an optional **supplementary international search** is performed by an international authority other than the International Searching Authority responsible for the establishment of the international search report. The international search report will be the main search, but applicants may be interested in requesting one or more supplementary international searches to expand the linguistic scope of the search. Unlike the international search report, the supplementary international search report is not accompanied by a written opinion.

Rule 45bis PCT Supplementary International Searches

The supplementary international search permits the applicant to request, in addition to the international search carried out under Article 15 PCT (the “main international search”), one or more supplementary international searches, each to be carried out by an international authority other than the International Searching Authority that carried out the main international search.

International publication

Article 29 PCT
Effects of the international publication
→ see below

The publication of the international application by the International Bureau (WIPO) takes place promptly after the expiration of 18 months from the priority date.

Article 29 PCT Effects of the international publication

(1) As far as the protection of any rights of the applicant in a designated State is concerned, the effects, in that State, of the international publication of an international application shall, subject to the provisions of paragraphs (2) to (4), be the same as those which the national law of the designated State provides for the compulsory national publication of unexamined national applications as such. [...]

Languages

Rule 48(3) PCT
Languages of publication
→ see below

Whether an international application may be filed in a specific language depends on the languages accepted by the receiving Office concerned for the filing of international applications. The EPO acting as receiving Office only accepts international applications filed in English, French or German.

The language of publication of the international application is not always the language in which the international application was filed. The current languages of publication are Arabic, Chinese, English, French, German, Japanese, Korean, Portuguese, Russian and Spanish.

Rule 48.3 PCT

Languages of publication

- (a) If the international application is filed in Arabic, Chinese, English, French, German, Japanese, Korean, Portuguese, Russian or Spanish ("languages of publication"), that application shall be published in the language in which it was filed.
- (b) If the international application is not filed in a language of publication and a translation into a language of publication has been furnished under Rule 12.3 or 12.4, that application shall be published in the language of that translation.
- (c) If the international application is published in a language other than English, the international search report to the extent that it is published under Rule 48.2(a)(v), or the declaration referred to in Article 17(2)(a), the title of the invention, the abstract and any text matter pertaining to the figure or figures accompanying the abstract shall be published both in that language and in English. The translations, if not furnished by the applicant under Rule 12.3, shall be prepared under the responsibility of the International Bureau.

Third-party observations

During the international phase, third parties may file observations on an international application.

The observations may be filed anonymously. No fee is due for filing such observations.

Administrative instructions under the PCT,
Section 801

Third party observation system

→ see below

Administrative instructions under the PCT, Section 801

Third party observation system

- (a) The International Bureau shall provide an electronic system for third parties to make observations referring to prior art which they believe to be relevant to the question of whether the invention claimed in the international application is new and/or involves an inventive step ("third party observation system").
- (b) The third party observation system:
- (i) shall provide a third party with the option to remain anonymous;
 - (ii) shall allow observations to include a brief explanation of the relevance of each prior art document referred to in the observation and to include a copy of the prior art document;
 - (iii) may limit the number of prior art documents which may be referred to in one observation; and
 - (iv) may limit the number of observations permitted to be made in relation to one international application, per third party and in total.
- (c) The International Bureau shall take technical steps to prevent abuse of the third party observation system.
- (d) The International Bureau may temporarily or indefinitely suspend the use of the third party observation system if it considers it necessary to do so.

The international preliminary examination

Applicants may optionally file a demand requesting the **international preliminary examination** of an international application to obtain a preliminary and non-binding opinion on whether the claimed invention appears to meet the patentability requirements.

Article 32 PCT
The International Preliminary Examining Authority
→ see below

The usefulness of this optional procedure depends on the outcome of the international search. International preliminary examination will, in general, have no added value unless amendments and/or arguments under Article 34 PCT are filed for the International Preliminary Examining Authority to take into account.

Article 33 PCT
The International Preliminary Examination
→ see below

Article 32 PCT **The International Preliminary Examining Authority**

- (1) International preliminary examination shall be carried out by the International Preliminary Examining Authority.
- (2) In the case of demands referred to in Article 31(2)(a), the receiving Office, and, in the case of demands referred to in Article 31(2)(b), the Assembly, shall, in accordance with the applicable agreement between the interested International Preliminary Examining Authority or Authorities and the International Bureau, specify the International Preliminary Examining Authority or Authorities competent for the preliminary examination.
- (3) The provisions of Article 16(3) shall apply, mutatis mutandis, in respect of International Preliminary Examining Authorities.

Article 33 PCT **The International Preliminary Examination**

- (1) The objective of the international preliminary examination is to formulate a preliminary and non-binding opinion on the questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), and to be industrially applicable.
- (2) For the purposes of the international preliminary examination, a claimed invention shall be considered novel if it is not anticipated by the prior art as defined in the Regulations.
- (3) For the purposes of the international preliminary examination, a claimed invention shall be considered to involve an inventive step if, having regard to the prior art as defined in the Regulations, it is not, at the prescribed relevant date, obvious to a person skilled in the art.
- (4) For the purposes of the international preliminary examination, a claimed invention shall be considered industrially applicable if, according to its nature, it can be made or used (in the technological sense) in any kind of industry. "Industry" shall be understood in its broadest sense, as in the Paris Convention for the Protection of Industrial Property.
- (5) The criteria described above merely serve the purposes of international preliminary examination. Any Contracting State may apply additional or different criteria for the purpose of deciding whether, in that State, the claimed invention is patentable or not.
- (6) The international preliminary examination shall take into consideration all the documents cited in the international search report. It may take into consideration any additional documents considered to be relevant in the particular case.

The national/regional phase

At the end of the international phase (at the latest), the applicant must decide whether and where he wants to proceed with the international application and, if so, enter into the national/regional phase before the respective designated or elected offices.

The applicant will then need to fulfill the specific national/regional requirements, such as the payment of fees and the filing of translations. The standard time limit for compliance with these requirements is 30 months from the priority date (**Article 22 PCT**).

If the applicant wishes to obtain a European patent, he must enter into the “European phase” with the EPO. The requirements in **Rule 159 EPC** must be fulfilled. At the EPO, the time limit for performing the required acts for entry into the regional phase is **31 months** from the priority date.

When deciding whether to grant the patent, the regional or national office is bound solely by its national law. However the international search report and the written opinion, as well as the optional international preliminary examination report, provide a strong basis for a decision.

Article 22 PCT
Copy, Translation, and Fee, to Designated Offices
→ see below

Article 27(5) PCT
National requirements
→ see below

Article 39 PCT
Copy, translation, and fee, to elected Offices
→ see below

Article 45(2) PCT
Regional patent treaties
[...]
(2) The national law of the said designated or elected State may provide that any designation or election of such State in the international application shall have the effect of an indication of the wish to obtain a regional patent under the regional patent treaty.

Rule 159 EPC
The European Patent Office as a designated or elected Office – Requirements for entry into the European phase
→ see below

Article 22 PCT **Copy, Translation, and Fee, to Designated Offices**

(1) The applicant shall furnish a copy of the international application (unless the communication provided for in Article 20 has already taken place) and a translation thereof (as prescribed), and pay the national fee (if any), to each designated Office not later than at the expiration of 30 months from the priority date. Where the national law of the designated State requires the indication of the name of and other prescribed data concerning the inventor but allows that these indications be furnished at a time later than that of the filing of a national application, the applicant shall, unless they were contained in the request, furnish the said indications to the national Office of or acting for the State not later than at the expiration of 30 months from the priority date. [...]

Article 27(5) PCT **National requirements**

[...] (5) Nothing in this Treaty and the Regulations is intended to be construed as prescribing anything that would limit the freedom of each Contracting State to prescribe such substantive conditions of patentability as it desires. In particular, any provision in this Treaty and the Regulations concerning the definition of prior art is exclusively for the purposes of the international procedure and, consequently, any Contracting State is free to apply, when determining the patentability of an invention claimed in an international application, the criteria of its national law in respect of prior art and other conditions of patentability not constituting requirements as to the form and contents of applications.

Article 39 PCT

Copy, translation, and fee, to elected Offices

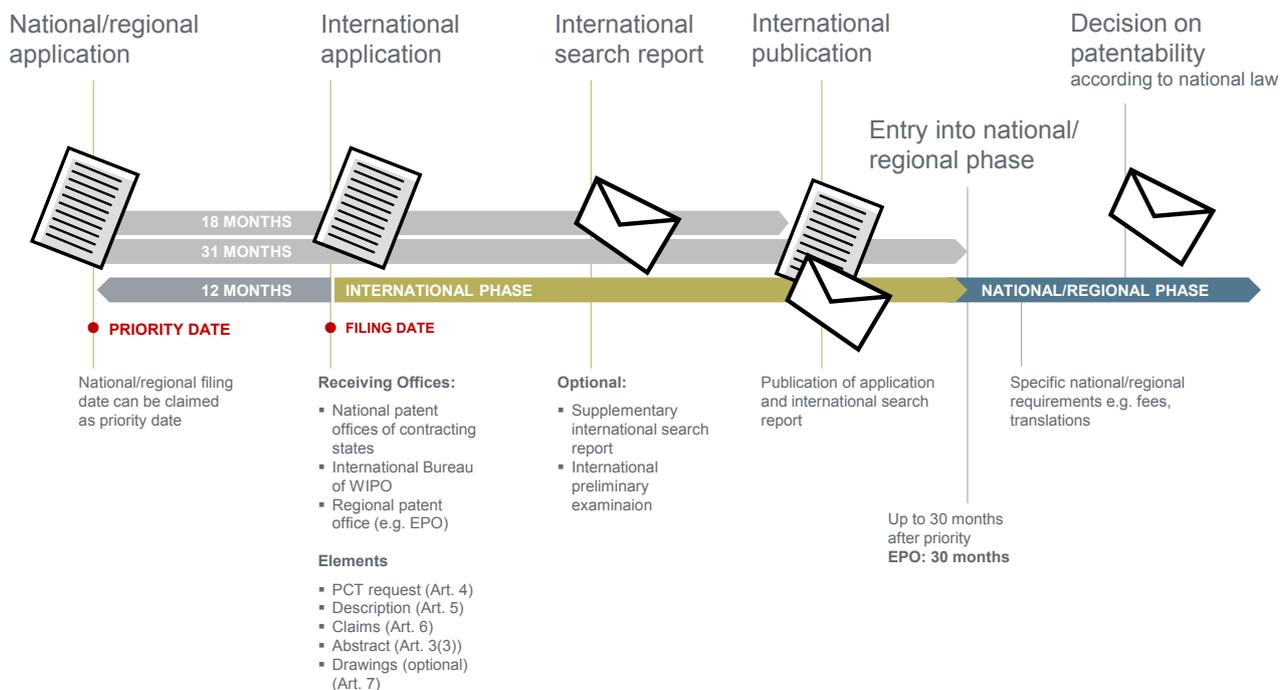
- (1) (a) If the election of any Contracting State has been effected prior to the expiration of the 19th month from the priority date, the provisions of Article 22 shall not apply to such State and the applicant shall furnish a copy of the international application (unless the communication under Article 20 has already taken place) and a translation thereof (as prescribed), and pay the national fee (if any), to each elected Office not later than at the expiration of 30 months from the priority date.
 - (b) Any national law may, for performing the acts referred to in subparagraph (a), fix time limits which expire later than the time limit provided for in that subparagraph.
- (2) The effect provided for in Article 11(3) shall cease in the elected State with the same consequences as the withdrawal of any national application in that State if the applicant fails to perform the acts referred to in paragraph (1)(a) within the time limit applicable under paragraph (1)(a) or (b).
- (3) Any elected Office may maintain the effect provided for in Article 11(3) even where the applicant does not comply with the requirements provided for in paragraph (1)(a) or (b).

Rule 159 EPC

The European Patent Office as a designated or elected Office – Requirements for entry into the European phase

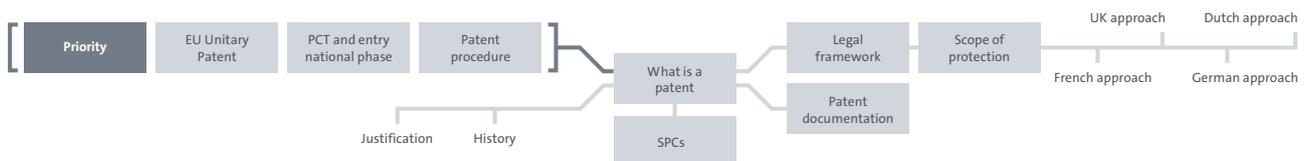
- (1) In respect of an international application under Article 153, the applicant shall perform the following acts within thirty-one months from the date of filing of the application or, if priority has been claimed, from the priority date:
 - (a) supply, where applicable, the translation of the international application required under Article 153, paragraph 4; [...]

Applying for a patent under the PCT



Priority

Essentials: Priority



Introduction

Due to the globalisation of markets and the increase in international trade, by the end of the 19th century there was a growing need for common international standards in applying for and protecting patents and other intellectual property rights. In particular, inventors who wanted to obtain patent protection for an invention in more than one country faced the problem that a patent application they filed in one country could be deemed to be novelty-destroying prior art in another country, if the application was filed subsequently in that other country. But national and translation requirements made it difficult for inventors to file patent applications for the same invention at the same time in more than one country. Consequently, whenever an invention was put on a particular market shortly after the first patent application was filed, the invention was no longer patentable in some of the other intended markets.

In order to solve this problem and to safeguard inventors' interests, the **Paris Convention** for the Protection of Industrial Property, concluded in 1883, introduced the concept of priority rights for patent applicants on an international level.

According to this **priority right**, anyone who files a patent application has the right to file an identical application in another signatory country of the Paris Convention within a certain time frame without being exposed to the risk that their own first application may be assessed as novelty-destroying in subsequent application procedures in other jurisdictions.

Consequently, the main effect of **priority right** is that, in terms of novelty, the filing date of the first application is considered to be the effective date for determining the state of the art of the subsequent applications within

Novelty

An invention can be patented only if it is new. An invention is not new and therefore not patentable if it was known to the public before the filing date, or before the priority date if priority of an earlier patent is claimed.

Paris Convention

The Paris Convention for the Protection of Industrial Property introduced the priority right for patents on an international level in 1883.

twelve months. The filing date of the first application is then defined as the priority date for any subsequent application for the same invention.

However, inventors need to be aware that priority right is a right limited by time. The time period for claiming priority for patent applications is twelve months. This period gives applicants the chance to identify market opportunities for their invention, continue development of the product or process and/or decide in which countries patent protection appears reasonable.

For inventors seeking patent protection for the same invention in more than one country, the principle of priority is very useful, as they do not have to file the application in all the countries concerned at the same time. As the first application is considered to have priority over subsequently filed applications and publications, the inventor will be considered as being the first to file in other countries, even if other applications are filed or relevant documents published in the meantime.

Definition

The priority date is the first date of filing of a patent application. It is essential for determining whether any subsequent application for the same invention can still be assessed as novel. It also makes it possible to determine whether the subject-matter of a patent application is prior art on a particular date.

The priority date is, however, not necessarily the same as the filing date.

The filing date of a patent application is the date the patent application was filed with the patent office, i.e. the date on which that application was legally accepted by that patent office. It is usually the date on which the documents are filed with the patent office. It may also be later, if there are formal errors in the application or certain documents are missing.

The filing date is usually the same as the priority date if the patent application is an original, non-provisional patent application, not a continuation application, and not previously filed in another country.

Legal basis

There are various types of priority right, with different legal bases.

1. Paris Convention

The Paris Convention is a multilateral arrangement between (currently) 175 contracting parties. One of its most important regulations is Article 4.

In essence, **Article 4** of the Paris Convention states that if an intellectual property right – in this case a patent – has been filed in one of the signatory countries, the applicant may claim priority for any subsequent identical application within twelve months, starting from the date of filing of the earlier application.

2. European Patent Convention

The European Patent Convention (EPC) is an international treaty that sets out a priority right system for first filings in or for states which are party to the Paris Convention or any member of the World Trade Organization (WTO). Article 87(1) EPC reads as follows:

"Any person who has duly filed, in or for

(a) any State party to the Paris Convention for the Protection of Industrial Property or

(b) any Member of the World Trade Organization,

an application for a patent, a utility model or a utility certificate, or his successor in title, shall enjoy, for the purpose of filing a European patent application in respect of the same invention, a right of priority during a period of twelve months from the date of filing of the first application."

According to Article 88(2) EPC, it is even possible to claim multiple priorities of a patent application or a patent claim, meaning that an applicant may claim more than one priority based on previous applications in the same or different states and/or WTO members.

The effect of priority right according to the EPC is that the date of priority counts as the date of filing of the European patent application for the purposes of Article 54(2) and (3) and Article 60(2) (see Article 89 EPC).

The procedure for claiming priority for a European patent is laid down in Article 88 EPC and the Implementing Regulations.

Article 4 Paris Convention

(A)

Any person who has duly filed an application for a patent, [...], in one of the countries of the Union, or his successor in title, shall enjoy, for the purpose of filing in the other countries, a right of priority during the periods hereinafter fixed.

(B)

Consequently, any subsequent filing in any of the other countries of the Union before the expiration of the periods referred to above shall not be invalidated by reason of any acts accomplished in the interval, in particular, another filing, the publication or exploitation of the invention, the putting on sale of copies of the design, or the use of the mark, and such acts cannot give rise to any third-party right or any right of personal possession.

(C)

The periods of priority referred to above shall be twelve months for patents and utility models [...],

These periods shall start from the date of filing of the first application; the day of filing shall not be included in the period. [...].

Guidelines for Examination in the European Patent Office

www.epo.org/law-practice/legal-texts/guidelines.html

3. Patent Cooperation Treaty

The Patent Cooperation Treaty is an international patent law treaty. A PCT application establishes a single filing date in all contracting states and essentially leads to a standard national or regional patent application, which may be granted or rejected according to the applicable law in the relevant jurisdiction in which a patent is desired. As set out in **Article 8(1)** PCT, any such application may contain a declaration claiming a priority right based on an earlier patent application.

Article 8 PCT

Claiming priority

(1) The international application may contain a declaration, as prescribed in the Regulations, claiming the priority of one or more earlier applications filed in or for any country party to the Paris Convention for the Protection of Industrial Property.

4. Domestic priority rights

Some jurisdictions provide for a domestic priority right that allows inventors to claim the priority of a first application when filing a subsequent application within the same jurisdiction. For example, **Section 40** of the German patent law allows for the opportunity to claim a domestic priority.

Section 40(1)

German Patent Act

Within a period of 12 months from the filing date of an earlier patent or utility model application filed with the Patent Office, the applicant is entitled to a priority right with respect to the application for the same invention unless a domestic or foreign priority was already claimed for the earlier application.

Claiming priority

In order to claim priority rights, applicants must fulfil certain conditions. For a European patent, these conditions are laid down in Articles 87 and 88 EPC.

1. Timeline for claiming priority rights

Applications claiming priority of an earlier application must be filed within 12 months of the date of filing of the earlier application.

2. Substantive requirements

(a) Earlier application

In order to claim priority, an earlier application for the same patent must have been filed. An earlier application is any patent application which is duly filed with a patent office and whose application date is earlier than the application date of the subsequent application.

Applications for which a domestic or foreign priority has already been claimed are excluded.

(b) Identity of the applicant

The right to priority can only be claimed by the applicant who filed the priority application or their successor in title.

(c) Identity of invention

In order for a priority right to be claimed, there must also be identity of invention. “Identity of invention” or “same invention” is established if the earlier application substantially refers to the same invention as the subsequent invention. A literal identity of any subsequent application is not required. However, any changes in the subsequent application must still refer to the same invention as disclosed in the earlier application.

In other words, priority of an earlier application can only be claimed if the person skilled in the art can derive the subject-matter of the claim directly and unambiguously from the earlier application by using no more than his common general knowledge. This means that all the elements of the newly worded claim must have been disclosed, explicitly or implicitly, in the earlier application, i.e. it must be what is called an enabling disclosure.

According to the Enlarged Board of Appeal of the EPO in **G 2/98**, priority is effective “only if the skilled person can derive the subject-matter of the claim directly and unambiguously, using common general knowledge, from the previous application as a whole”.

Opinion of the Enlarged Board of Appeal of the EPO dated 31 May 2001, G 2/98
www.epo.org/law-practice/case-law-appeals/pdf/g980002ep1.pdf

In contrast, identity of invention is not possible if the invention disclosed in the subsequent application is characterised by additional features.

(d) Disclosure of characteristics

The right to priority is provided only for characteristics sufficiently disclosed in the patent application for them to be appreciated by a person skilled in the art.

The scope of the disclosure in the earlier application is determined from the application documents, i.e. the description, claims and drawings.

3. Formal requirements

In order to claim priority, the following must be provided:

- A declaration that priority is claimed.
- Information about the file number of the earlier application.
- A copy of the previous application.
- If necessary: a translation of the earlier application.

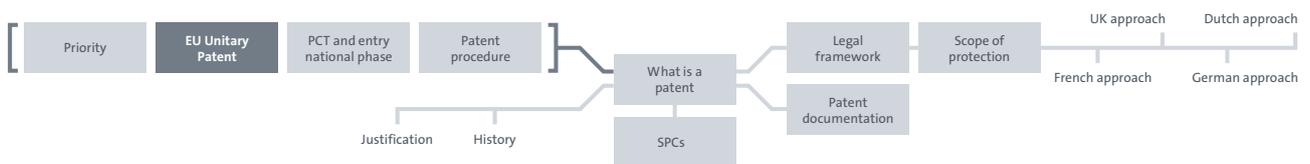
Summary

The major advantages and effects of priority right are:

- The filing date of the first application counts as the date by which the state of the art is assessed against the application.
- Applicants have, during the priority period of twelve months, time to evaluate the commercial potential of the invention, to continue developing it and to decide in which countries subsequent patent applications for the same invention should be filed.
- Applicants can postpone spending time and money on foreign patent application procedures until they have received a first report on the patentability of the invention.
- Applicants can make their invention public without generating novelty-destroying prior art in respect of any subsequent patent application within twelve months.
- Applicants can maintain the novelty of their inventions for subsequent patent applications filed elsewhere within twelve months, even if someone else has applied to patent the same or a similar invention in the meantime.

EU Unitary Patent

Essentials: The unitary patent



Introduction

The creation of unitary patent protection for the territory of the European Community/Union has been under discussion since the end of the 1950s. In the 1970s, the plan was that the Community Patent Convention (CPC) and, at a later stage, its Litigation Protocol would complement the EPC and provide a unitary patent for the whole European Community, together with a common court of appeal. However, despite various attempts, the CPC never entered into force, because it neither simplified nor improved on the European patent system.

In 2000, the European Commission reacted to this unsatisfactory situation by presenting a draft proposal for a Regulation on the Community Patent centred on the idea that the EU could accede to the EPC and could thus be designated, as a whole, for the grant of a European patent. Following criticism of the complicated and expensive nature of the previous proposed litigation system and language regime, the Commission this time favoured the three-language regime of the EPC.

In the course of subsequent discussions, it became clear that the problems relating to the language regime and litigation system could not be settled. This caused the Council to state, at the end of 2010, that “insurmountable obstacles to unanimity will persist for the foreseeable future”.

The way forward from 2011: enhanced co-operation

The issue of the language regime proved to be a major turning point for the unitary patent, because it prompted a group of EU member states to formally address to the Commission a request for “enhanced co-operation” according to **Article 20 TEU** and Articles 326-334 TFEU.

Article 20 TEU
→ see below

Enhanced co-operation allows those EU member states participating in it to make use of the EU’s institutions and to adopt legislation in a specific area, with others able to opt in at a later stage.

Only a few months later, by decision of 10 March 2011, the Council granted authorisation to proceed with enhanced co-operation. Out of the 28 EU member states, only Spain and Croatia have not yet joined the scheme. Italy, which initially decided not to participate, joined in autumn 2015.

Acts adopted within the framework of enhanced co-operation are binding on participating member states only, so the unitary patent will take effect in the territories of these states only.

Article 20 TEU

(1) Member States which wish to establish enhanced cooperation between themselves within the framework of the Union’s non-exclusive competences may make use of its institutions and exercise those competences by applying the relevant provisions of the Treaties, subject to the limits and in accordance with the detailed arrangements laid down in this Article and in Articles 326 to 334 of the Treaty on the Functioning of the European Union.

Enhanced cooperation shall aim to further the objectives of the Union, protect its interests and reinforce its integration process. Such cooperation shall be open at any time to all Member States, in accordance with Article 328 of the Treaty on the Functioning of the European Union.

(2) The decision authorising enhanced cooperation shall be adopted by the Council as a last resort, when it has established that the objectives of such cooperation cannot be attained within a reasonable period by the Union as a whole, and provided that at least nine Member States participate in it. [...]

(3) All members of the Council may participate in its deliberations, but only members of the Council representing the Member States participating in enhanced cooperation shall take part in the vote. [...]

(4) Acts adopted in the framework of enhanced cooperation shall bind only participating Member States. They shall not be regarded as part of the *acquis* which has to be accepted by candidate States for accession to the Union.

The tripartite “Unitary patent package”

In April 2011, the EU Commission proposed two draft regulations for implementing enhanced co-operation in the area of the creation of unitary patent protection, one of them creating unitary patent protection (**Regulation (EU) No. 1257/2012**) and the other specifying the applicable translation arrangements (**Regulation (EU) No. 1260/2012**). Both regulations entered into force on 20 January 2013.

At the same time, an international treaty entitled the Agreement on a Unified Patent Court (UPC Agreement) was negotiated between the EU member states in order to set up a common European patent court.

The UPC Agreement is open to signature by all the EU member states, not just those participating in enhanced co-operation. On 19 February 2013 it was signed by all the member states participating in enhanced co-operation apart from Poland. Those contracting states to the EPC which are not members of the EU thus cannot accede to the Agreement.

In order for the Agreement to enter into force, it must be ratified by at least 13 contracting states, including France, Germany and the UK. A total of 16 states, including France, have ratified it to date, and the national ratification procedure is progressing rapidly in the other states.

As Regulations (EU) No. 1257/2012 and (EU) No. 1260/2012 and the UPC Agreement complement each other, they will enter into force once the UPC Agreement is ratified.

Regulation (EU) No 1257/2012, Recital 23

This Regulation is complemented by Regulation (EU) No. 1260/2012, adopted by the Council in accordance with the second paragraph of Article 118 TFEU.

Recital 24

Jurisdiction in respect of European patents with unitary effect should be established and governed by an instrument setting up a unified patent litigation system for European patents and European patents with unitary effect.

Recital 25

Establishing a Unified Patent Court to hear cases concerning the European patent with unitary effect is essential in order to ensure the proper functioning of that patent, consistency of case-law and hence legal certainty, and cost-effectiveness for patent proprietors. It is therefore of paramount importance that the participating Member States ratify the Agreement on a Unified Patent Court in accordance with their national constitutional and parliamentary procedures and take the necessary steps for that Court to become operational as soon as possible.

Regulation (EU) No 1260/2012, Recital 14

Since the substantive provisions applicable to a European patent with unitary effect are governed by Regulation (EU) No. 1257/2012 and are completed by the translation arrangements provided for in this Regulation, this Regulation should apply from the same date as Regulation (EU) No. 1257/2012.

Conditions for the registration of unitary effect

The unitary patent is a European patent to which, at the request of its proprietor, unitary effect is given. For unitary effect to be registered, therefore, a European patent has to have been applied for and granted under the rules of the EPC.

This approach means that applicants wanting unitary protection in the states participating in enhanced co-operation will first have to file a European or international application and get a patent granted by the EPO. They do not have to decide whether they want unitary effect for their European patent until such time as their patent is granted.

In order to register unitary effect, the patent proprietor must file a request for unitary effect in writing in the language of proceedings within one month of the date of publication of the mention of the grant of the European patent in the European Patent Bulletin. However, unitary effect can only be registered for the patent if it was granted with the same set of claims in all 26 participating states. If this is not the case, the EPO must reject the request for unitary effect.

The details of the procedure for registering unitary effect are set out in the Rules relating to Unitary Patent Protection, which were adopted as part of the secondary legislation.

They are available at
www.epo.org/law-practice/unitary/unitary-patent.html

Article 3 Regulation (EU) No. 1257/2012 European patent with unitary effect

(1) A European patent granted with the same set of claims in respect of all the participating Member States shall benefit from unitary effect in the participating Member States provided that its unitary effect has been registered in the Register for unitary patent protection.

A European patent granted with different sets of claims for different participating Member States shall not benefit from unitary effect.

(2) A European patent with unitary effect shall have a unitary character. It shall provide uniform protection and shall have equal effect in all the participating Member States.

It may only be limited, transferred or revoked, or lapse, in respect of all the participating Member States. It may be licensed in respect of the whole or part of the territories of the participating Member States.

(3) The unitary effect of a European patent shall be deemed not to have arisen to the extent that the European patent has been revoked or limited.

Translation arrangements

As regards the translation arrangements for the unitary patent, it was decided that no additional translations will be required, meaning that once the EPO grants a European patent in one of its official languages (English, French or German), the proprietor can get unitary protection without having to file any more translations. Instead, high-quality machine translations will be made available free of charge. The EPO, working with Google, has already launched a translation engine which provides translations from and into English, French and German for a total of 29 different languages.

The European legislator also provided for a transitional period of at least six but no more than twelve years, starting on the day of application of the EU unitary patent regulations. During this period, and until such time as high-quality machine translations are available, requests for registration of a unitary patent must be filed together with

- an English translation of the patent specification, if the patent was granted in French or German, or
- a translation into any other official EU language of the proprietor's choice, if the EPO granted the patent in English.

In the event of a dispute relating to a unitary patent, the proprietor may have to provide a full translation of the patent at his own cost. More precisely, in cases of alleged infringement, the patent proprietor may be asked by the alleged infringer to provide a translation, at the alleged infringer's choice into an official language either of the participating member state where the infringement took place or of the member state in which the alleged infringer is domiciled. Moreover, in the case of any dispute relating to a unitary patent, the proprietor may be asked by the competent court to provide a translation into the language of proceedings of that court.

Article 4 Translation in the event of a dispute

- (1) In the event of a dispute relating to an alleged infringement of a European patent with unitary effect, the patent proprietor shall provide at the request and the choice of an alleged infringer, a full translation of the European patent with unitary effect into an official language of either the participating Member State in which the alleged infringement took place or the Member State in which the alleged infringer is domiciled.
- (2) In the event of a dispute relating to a European patent with unitary effect, the patent proprietor shall provide in the course of legal proceedings, at the request of a court competent in the participating Member States for disputes concerning European patents with unitary effect, a full translation of the patent into the language used in the proceedings of that court.
- (3) The cost of the translations referred to in paragraphs 1 and 2 shall be borne by the patent proprietor.[...]

Article 3 Regulation (EU) No. 1260/2012 Translation arrangements for the European patent with unitary effect

(1) Without prejudice to Articles 4 and 6 of this Regulation, where the specification of a European patent, which benefits from unitary effect has been published in accordance with Article 14(6) of the EPC, no further translations shall be required.

(2) A request for unitary effect as referred to in Article 9 of Regulation (EU) No. 1257/2012 shall be submitted in the language of the proceedings.

Article 4 Translation in the event of a dispute → see below

Article 5 Administration of a compensation scheme

(1) Given the fact that European patent applications may be filed in any language under Article 14(2) of the EPC, the participating Member States shall in accordance with Article 9 of Regulation (EU) No. 1257/2012, give, within the meaning of Article 143 of the EPC, the EPO the task of administering a compensation scheme for the reimbursement of all translation costs up to a ceiling, for applicants filing patent applications at the EPO in one of the official languages of the Union that is not an official language of the EPO.

(2) The compensation scheme referred to in paragraph 1 shall be funded through the fees referred to in Article 11 of Regulation (EU) No. 1257/2012 and shall be available only for SMEs, natural persons, non-profit organisations, universities and public research organisations having their residence or principal place of business within a Member State.

Article 6 Transitional measures

(1) During a transitional period starting on the date of application of this Regulation a request for unitary effect as referred to in Article 9 of Regulation (EU) No 1257/2012 shall be submitted together with the following:

(a) where the language of the proceedings is French or German, a full translation of the specification of the European patent into English; or

(b) where the language of the proceedings is English, a full translation of the specification of the European patent into any other official language of the Union.
[...]

Effect of registering unitary effect

Unitary patents take effect retroactively from the date the EPO publishes the mention of the grant of the European patent in the European Patent Bulletin. Consequently, when a unitary patent is registered, the classical European patent is deemed not to have taken effect as a national patent on the territories of the participating member states to which the unitary effect extends.

As for their territorial scope of protection, unitary patents will cover the territories of the member states which, on the day of registration of unitary effect, are participating in enhanced co-operation *and* have ratified the UPC Agreement. As the latter Agreement will enter into force when 13 states, including France, Germany and the United Kingdom, have ratified it, there will be different “generations” of unitary patents covering the territories of those participating member states where the UPC Agreement takes effect at the time of registration of the unitary patent. Third parties will therefore have to consult the future Register for unitary patent protection, which will be incorporated into the European Patent Register, to find out which states a given unitary patent covers.

Regulation (EU) No. 1257/2012 stipulates that unitary patents will provide uniform protection and have equal effect in all the participating member states in which they take effect. Consequently, they may only be limited, transferred or revoked, or lapse, in respect of all the participating member states. The grounds for revocation remain those specified in the EPC, because the unitary patent is a European patent.

Unitary patents may be licensed for the whole or part of the territories of the member states. Furthermore, the EU regulations give proprietors the option of stating to the EPO that they will grant licences of right to any interested party in return for appropriate consideration. Where such a licence of right statement is provided by the patent proprietor, the renewal fees will be reduced by 15%.

Article 5 Uniform protection

- (1) The European patent with unitary effect shall confer on its proprietor the right to prevent any third party from committing acts against which that patent provides protection throughout the territories of the participating Member States in which it has unitary effect, subject to applicable limitations.
- (2) The scope of that right and its limitations shall be uniform in all participating Member States in which the patent has unitary effect.
- (3) The acts against which the patent provides protection referred to in paragraph 1 and the applicable limitations shall be those defined by the law applied to European patents with unitary effect in the participating Member State whose national law is applicable to the European patent with unitary effect as an object of property in accordance with Article 7.[...]

Article 4 Regulation (EU) 1257/2012

Date of effect

(1) A European patent with unitary effect shall take effect in the participating Member States on the date of publication by the EPO of the mention of the grant of the European patent in the European Patent Bulletin.

(2) The participating Member States shall take the necessary measures to ensure that, where the unitary effect of a European patent has been registered and extends to their territory, that European patent is deemed not to have taken effect as a national patent in their territory on the date of publication of the mention of the grant in the European Patent Bulletin.

Article 5

Uniform protection

→ see below

Article 7

Treating a European patent with unitary effect as a national patent

(1) A European patent with unitary effect as an object of property shall be treated in its entirety and in all the participating Member States as a national patent of the participating Member State in which that patent has unitary effect and in which, according to the European Patent Register:

(a) the applicant had his residence or principal place of business on the date of filing of the application for the European patent; or

(b) where point (a) does not apply, the applicant had a place of business on the date of filing of the application for the European patent.

[...]

(3) Where no applicant had his residence, principal place of business or place of business in a participating Member State in which that patent has unitary effect for the purposes of paragraphs 1 or 2, the European patent with unitary effect as an object of property shall be treated in its entirety and in all the participating Member States as a national patent of the State where the European Patent Organisation has its headquarters in accordance with Article 6(1) of the EPC.[...]

Unified payment of renewal fees

The renewal fees for the unitary patent were fixed at the so-called TOP 4 level, which provides for fee levels corresponding to the equivalent of the renewal fees which have to be paid for the four countries out of the 26 EU participating member states in which European patents were most often validated at the time the decision for enhanced co-operation was made (France, Germany, The Netherlands and the United Kingdom).

The renewal fees for the first ten years will be less than EUR 5 000, which is a business-friendly fee pattern.

While renewal fees for European patent *applications* are due at the EPO, those for granted classical European *patents* are due in each designated contracting state.

In contrast, the renewal fees for unitary patents will be collected and administered by the EPO, and will be due for the years following that in which the mention of the grant of the European patent with unitary effect is published in the European Patent Bulletin.

The EPO will keep 50% of renewal fee income and distribute the remaining 50%, after deducting the expenses incurred in carrying out its additional unitary patent tasks, to the participating member states in line with an agreed distribution key.

This secondary legislation was adopted by the Select Committee, which is a sub-body of the Administrative Council of the European Patent Organisation. It is composed of representatives of the 26 participating member states, and – as observers – of the EPC contracting states that do not participate in the unitary patent scheme, as well as user organisations.

Article 9 Regulation (EU) No. 1257/2012
Administrative tasks in the framework of
the European Patent Organisation

→ see below

Article 11 **Renewal fees**

(1) Renewal fees for European patents with unitary effect and additional fees for their late payment shall be paid to the European Patent Organisation by the patent proprietor. Those fees shall be due in respect of the years following the year in which the mention of the grant of the European patent which benefits from unitary effect is published in the European Patent Bulletin.

(2) A European patent with unitary effect shall lapse if a renewal fee and, where applicable, any additional fee have not been paid in due time.

[...]

Article 9 Regulation (EU) No 1257/2012 **Administrative tasks in the framework of the European Patent Organisation**

(1) The participating Member States shall, within the meaning of Article 143 of the EPC, give the EPO the following tasks, to be carried out in accordance with the internal rules of the EPO: [...]

- (e) to collect and administer renewal fees for European patents with unitary effect, in respect of the years following the year in which the mention of the grant is published in the European Patent Bulletin; to collect and administer additional fees for late payment of renewal fees where such late payment is made within six months of the due date, as well as to distribute part of the collected renewal fees to the participating Member States; [...]

The Unified Patent Court: structure, location, composition

The UPC Agreement establishes a new international judiciary, namely a unified patent court (UPC) with legal personality for the EU member states which have ratified the Agreement, whether or not they participate in the enhanced co-operation creating the unitary patent system.

The UPC will comprise a Court of First Instance, a Court of Appeal and a Registry.

The Court of First Instance will be decentralised. It will have a central division and local and regional divisions in the contracting states at their request.

The Court of Appeal will be centralised and located in Luxembourg. The Registry will be set up at the Court of Appeal, with sub-registries at all divisions of the Court of First Instance.

Furthermore, a mediation and arbitration centre will be established with seats in Lisbon and Ljubljana, and there will be a training centre for judges in Budapest.

As for the composition of the panels of the Court of First Instance, they will be formed of three judges of at least two different nationalities. In the case of local and regional divisions, the three judges will be legally trained, unless the panel asks the President of the Court of First Instance to allocate a technically trained judge from the pool of judges. In the case of the central division, two of the judges will be legally trained and the third one technically trained, unless the appeal concerns decisions of the EPO related to its administrative tasks within the unitary patent system, in which case the panel will comprise three legally trained judges.

The panels of the Court of Appeal will be composed of three legally trained and two technically trained judges, unless the appeal concerns decisions of the EPO related to its administrative tasks within the unitary patent system, in which case three legally trained judges will hear the appeal.

All panels will be chaired by a legally trained judge.

Article 1 UPC Agreement Unified Patent Court

A Unified Patent Court for the settlement of disputes relating to European patents and European patents with unitary effect is hereby established.
[...]

Article 4 Legal status

(1) The Court shall have legal personality in each Contracting Member State and shall enjoy the most extensive legal capacity accorded to legal persons under the national law of that State.

(2) The Court shall be represented by the President of the Court of Appeal who shall be elected in accordance with the Statute.

Article 6 The Court

(1) The Court shall comprise a Court of First Instance, a Court of Appeal and a Registry.

(2) The Court shall perform the functions assigned to it by this Agreement.

Jurisdiction of the UPC

The UPC will have exclusive jurisdiction in the territory of the contracting states in respect of classical European patents, unitary patents and supplementary protection certificates (SPCs).

Thus, the UPC will have exclusive competence in respect of

- Actions for infringement or threatened infringement.
- Actions for declaration of non-infringement.
- Actions for provisional and protective measures and injunctions.
- Actions or counterclaims for revocation.
- Appeals against decisions taken by the EPO in carrying out its additional tasks relating to unitary patents. In such cases, the UPC will act as an administrative court. Such actions (ex post) will only be dealt with by the central division at first instance.

Cases before the Court of First Instance will in general be assigned to the local or regional divisions at the *forum rei* or the *forum delicti*; actions against defendants domiciled outside the territory of application of the UPC can be brought before the *forum delicti* or the central division.

In the case of counterclaims for revocation in infringement proceedings, the local or regional division dealing with the infringement could:

- proceed with both the infringement action and the counterclaim for revocation, for which it would need to ask the President of the Court of First Instance to allocate a technically trained judge qualified and experienced in the field of technology concerned, refer the counterclaim for decision to the central division and suspend or proceed with the infringement proceedings; or
- with the agreement of the parties, refer the whole case to the central division.

Thus, the court's local and regional divisions will have the choice to either accept a technical judge on their panel, or to split ("bifurcate") the infringement and revocation proceedings.

The competence of the central division is subdivided between its seat in Paris and sections in London and Munich, depending on the nature of the patented invention:

- Paris will host the Court of First Instance's President's Office and deal with disputes concerning patents relating to performing operations, transporting, textiles, paper, fixed constructions, physics and electricity.
- London will deal with disputes concerning patents relating to human necessities, chemistry and metallurgy.
- Munich will deal with disputes concerning patents relating to mechanical engineering, lighting, heating, weapons and blasting.

Article 3 UPC Agreement

Scope of application

This Agreement shall apply to any:

- (a) European patent with unitary effect;
- (b) supplementary protection certificate issued for a product protected by a patent;
- (c) European patent which has not yet lapsed at the date of entry into force of this Agreement or was granted after that date, without prejudice to Article 83; and
- (d) European patent application which is pending at the date of entry into force of this Agreement or which is filed after that date, without prejudice to Article 83.

Article 32

Competence of the Court

→ see below

Article 33

Competence of the divisions of the Court of First Instance

→ see below

Article 32

Competence of the Court

The Court shall have exclusive competence in respect of:

- (a) actions for actual or threatened infringements of patents and supplementary protection certificates and related defences, including counterclaims concerning licences;
- (b) actions for declarations of non-infringement of patents and supplementary protection certificates;
- (c) actions for provisional and protective measures and injunctions;
- (d) actions for revocation of patents and for declaration of invalidity of supplementary protection certificates;
- (e) counterclaims for revocation of patents and for declaration of invalidity of supplementary protection certificates;
- (f) actions for damages or compensation derived from the provisional protection conferred by a published European patent application;
- (g) actions relating to the use of the invention prior to the granting of the patent or to the right based on prior use of the invention;
- (h) actions for compensation for licences on the basis of Article 8 of Regulation (EU) No 1257/2012; and
- (i) actions concerning decisions of the European Patent Office in carrying out the tasks referred to in Article 9 of Regulation (EU) No 1257/2012. [...]

Article 33

Competence of the divisions of the Court of First Instance

- (1) Without prejudice to paragraph 6 of this Article, actions referred to in Article 32(1)(a), (c), (f) and (g) shall be brought before:
 - (a) the local division hosted by the Contracting Member State where the actual or threatened infringement has occurred or may occur, or the regional division in which that Contracting Member State participates; or
 - (b) the local division hosted by the Contracting Member State where the defendant or, in the case of multiple defendants, one of the defendants has its residence, or principal place of business, or in the absence of residence or principal place of business, its place of business, or the regional division in which that Contracting Member State participates. [...].

Actions referred to in Article 32(1)(h) shall be brought before the local or regional division in accordance with point (b) of the first subparagraph.

Actions against defendants having their residence, or principal place of business or, in the absence of residence or principal place of business, their place of business, outside the territory of the Contracting Member States shall be brought before the local or regional division in accordance with point (a) of the first subparagraph or before the central division.

If the Contracting Member State concerned does not host a local division and does not participate in a regional division, actions shall be brought before the central division. [...]

- (3) A counterclaim for revocation as referred to in Article 32(1)(e) may be brought in the case of an action for infringement as referred to in Article 32(1)(a). The local or regional division concerned shall, after having heard the parties, have the discretion either to:
 - (a) proceed with both the action for infringement and with the counterclaim for revocation and request the President of the Court of First Instance to allocate from the Pool of Judges in accordance with Article 18(3) a technically qualified judge with qualifications and experience in the field of technology concerned.
 - (b) refer the counterclaim for revocation for decision to the central division and suspend or proceed with the action for infringement; or
 - (c) with the agreement of the parties, refer the case for decision to the central division.

Proceedings before the UPC

The UPC will work to its own rules of procedure, which are currently being drawn up by the UPC preparatory committee. They are based on the fundamental procedural rules set out in the Agreement itself.

These include:

- General procedural principles (proportionality and fairness, case management, public hearings).
- Entitlement to appear as a party before the court.
- The principle of a three-step procedure (written, interim and oral procedures).
- Means of evidence.
- Powers of the UPC.
- Language of proceedings.
- Representation.

The UPC will, *inter alia*, have the power to

- Order injunctions and other measures (e.g. forfeiture, indemnification of a party, right to information).
- Issue provisional and protective measures (e.g. seizure of the defendant's assets, inspection of the defendant's property).
- Award damages and compensation.

As for procedural remedies, any party which has been unsuccessful in its submissions, in whole or in part, before the Court of First Instance can appeal the latter's decision within two months before the Court of Appeal. The appeal can be based on points of law or matters of fact. It has no suspensive effect, unless it is directed against a decision on revocation or against a decision on a decision of the EPO, or unless the Court of Appeal decides otherwise at the "motivated request" of one of the parties.

As a further, extraordinary, remedy, a "rehearing" may exceptionally be granted by the Court of Appeal if, after the Court's final decision, the party requesting the rehearing either can demonstrate a fundamental procedural defect or has discovered a fact which is liable to be a decisive factor but was unknown to the party when the decision was handed down. The rehearing does not have suspensive effect, unless the Court of Appeal decides otherwise.

The UPC's fees combine fixed fees with a value-based component. They take into account the particular situation of SMEs, in that court fees are lower for disputes concerning smaller values.

Article 41 UPC Agreement Rules of Procedure

(1) The Rules of Procedure shall lay down the details of the proceedings before the Court. They shall comply with this Agreement and the Statute.

Article 48 Representation

(1) Parties shall be represented by lawyers authorised to practise before a court of a Contracting Member State.

(2) Parties may alternatively be represented by European Patent Attorneys who are entitled to act as professional representatives before the European Patent Office [...].

[...]

(4) Representatives of the parties may be assisted by patent attorneys [...].

Article 56

The general powers of the Court

(1) The Court may impose such measures, procedures and remedies as are laid down in this Agreement and may make its orders subject to conditions, in accordance with the Rules of Procedure.[...]

Article 69

Legal costs

(1) Reasonable and proportionate legal costs and other expenses incurred by the successful party shall, as a general rule, be borne by the unsuccessful party, unless equity requires otherwise, up to a ceiling set in accordance with the Rules of Procedure.[...]

Article 73

Appeal

→ see below

Article 74

Effect of an appeal

→ see below

Article 81

Rehearing

→ see below

With the exception of proceedings related to appeals against decisions of the EPO, representation is mandatory. Parties can be represented by:

- Lawyers authorised to practise before a court of a contracting state to the UPC Agreement.
- Patent attorneys who are entitled to act as professional representatives before the EPO and who have appropriate qualifications in patent litigation, i.e. who have acquired the European Patent Litigation Certificate.

In addition, representatives of the parties may be assisted by patent attorneys, who will be allowed to speak at hearings of the court.

Article 73 Appeal

- (1) An appeal against a decision of the Court of First Instance may be brought before the Court of Appeal by any party which has been unsuccessful, in whole or in part, in its submissions, within two months of the date of the notification of the decision.
- (2) An appeal against an order of the Court of First Instance may be brought before the Court of Appeal by any party which has been unsuccessful, in whole or in part, in its submissions [...].
- (3) The appeal against a decision or an order of the Court of First Instance may be based on points of law and matters of fact.[...]

Article 74 Effect of an appeal

- (1) An appeal shall not have suspensive effect unless the Court of Appeal decides otherwise at the motivated request of one of the parties. The Rules of Procedure shall guarantee that such a decision is taken without delay.[...]

Article 81 Rehearing

- (1) A request for rehearing after a final decision of the Court may exceptionally be granted by the Court of Appeal in the following circumstances:
 - (a) on discovery of a fact by the party requesting the rehearing, which is of such a nature as to be a decisive factor and which, when the decision was given, was unknown to the party requesting the rehearing; such request may only be granted on the basis of an act which was held, by a final decision of a national court, to constitute a criminal offence; or
 - (b) in the event of a fundamental procedural defect, in particular when a defendant who did not appear before the Court was not served with the document initiating the proceedings or an equivalent document in sufficient time and in such a way as to enable him to arrange for the defence.
- (2) A request for a rehearing shall be filed within 10 years of the date of the decision but not later than two months from the date of the discovery of the new fact or of the procedural defect. Such request shall not have suspensive effect unless the Court of Appeal decides otherwise.[...]

Language of proceedings

Before the local and regional divisions of the Court of First Instance, the language of proceedings will normally be the official language of the contracting state hosting the division. It can also be one of the official languages of the EPO designated by the member state hosting the local division or by the member states sharing a regional division.

Before the central division, the language of proceedings will be the language in which the patent concerned was granted.

Before the Court of Appeal, the language of proceedings will usually be the one used before the Court of First Instance, unless the parties agree on using the language in which the patent was granted or the Court of Appeal decides exceptionally on another language of proceedings.

Article 49 UPC Agreement
Language of proceedings at the Court of First Instance
→ see below

Article 50
Language of proceedings at the Court of Appeal
(1) The language of proceedings before the Court of Appeal shall be the language of proceedings before the Court of First Instance.[...]

Article 51
Other language arrangements
→ see below

Article 49 **Language of proceedings at the Court of First Instance**

- (1) The language of proceedings before any local or regional division shall be an official European Union language which is the official language or one of the official languages of the Contracting Member State hosting the relevant division, or the official language(s) designated by Contracting Member States sharing a regional division.[...]
- (3) The parties may agree on the use of the language in which the patent was granted as the language of proceedings[...].
- (4) With the agreement of the parties the competent panel may, on grounds of convenience and fairness, decide on the use of the language in which the patent was granted as the language of proceedings.
- (5) At the request of one of the parties and after having heard the other parties and the competent panel, the President of the Court of First Instance may [...] decide on the use of the language in which the patent was granted as language of proceedings. [...]
- (6) The language of proceedings at the central division shall be the language in which the patent concerned was granted.

Article 51 **Other language arrangements**

- (1) Any panel of the Court of First Instance and the Court of Appeal may, to the extent deemed appropriate, dispense with translation requirements.
- (2) At the request of one of the parties, and to the extent deemed appropriate, any division of the Court of First Instance and the Court of Appeal shall provide interpretation facilities to assist the parties concerned at oral proceedings.
- (3) Notwithstanding Article 49(6), in cases where an action for infringement is brought before the central division, a defendant having its residence, principal place of business or place of business in a Member State shall have the right to obtain, upon request, translations of relevant documents in the language of the Member State of residence, principal place of business or, in the absence of residence or principal place of business, place of business, in the following circumstances:[...].

Relationship between the UPC and the Court of Justice of the EU (CJEU)

The UPC will be a court common to the EU member states. Like every national court of the EU member states, it therefore has the duty under the EU Treaties to respect the primacy of and apply EU law in its rulings, and to refer questions on the interpretation of EU law to the CJEU and ask for preliminary rulings. The contracting states to the UPC Agreement recognise those duties and their liability in the event of violation of EU law by the UPC.

Article 1 UPC Agreement Unified Patent Court [...]

(2) The Unified Patent Court shall be a court common to the Contracting Member States and thus subject to the same obligations under Union law as any national court of the Contracting Member States.

Remaining jurisdiction of national courts

The national courts will retain jurisdiction for all actions concerning classical European and unitary patents which do not come within the exclusive jurisdiction of the UPC. These include actions relating to the patent as an object of property.

In addition, the UPC Agreement provides for a transitional period of seven years after its entry into force, extendable by another seven years, during which infringement and revocation proceedings concerning classical European patents, but *not* unitary patents, may still be initiated before the national courts (or other competent authorities) of a contracting state having jurisdiction.

Furthermore, proprietors of classical European patents granted or applied for prior to the end of the transitional period, but *not* proprietors of unitary patents, will have the possibility to opt out from the scope of application of the UPC Agreement at the latest one month before expiry of the transitional period by notifying the Registry. This opt-out can be withdrawn at any moment, unless an action relating to the patent concerned has already been brought before a national court.

Article 32 Competence of the Court [...]

(2) The national courts of the Contracting Member States shall remain competent for actions relating to patents and supplementary protection certificates which do not come within the exclusive competence of the Court.

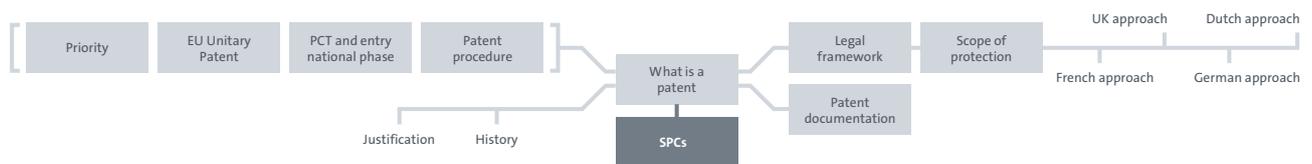
Article 83 Transitional regime → see below

Article 83 Transitional regime

- (1) During a transitional period of seven years after the date of entry into force of this Agreement, an action for infringement or for revocation of a European patent or an action for infringement or for declaration of invalidity of a supplementary protection certificate issued for a product protected by a European patent may still be brought before national courts or other competent national authorities.
- (2) An action pending before a national court at the end of the transitional period shall not be affected by the expiry of this period.
- (3) Unless an action has already been brought before the Court, a proprietor of or an applicant for a European patent granted or applied for prior to the end of the transitional period under paragraph 1 and, where applicable, paragraph 5, as well as a holder of a supplementary protection certificate issued for a product protected by a European patent, shall have the possibility to opt out from the exclusive competence of the Court. To this end they shall notify their opt-out to the Registry by the latest one month before expiry of the transitional period. The opt-out shall take effect upon its entry into the register.
- (4) Unless an action has already been brought before a national court, proprietors of or applicants for European patents or holders of supplementary protection certificates issued for a product protected by a European patent who made use of the opt-out in accordance with paragraph 3 shall be entitled to withdraw their opt-out at any moment. In this event they shall notify the Registry accordingly. The withdrawal of the opt-out shall take effect upon its entry into the register.[...]

Supplementary protection certificates

Essentials: SPCs



Introduction

The term of protection of a patent is 20 years from the date of filing of the application. In the life sciences industry, however, the period of effective patent protection is significantly less than in other industry sectors, because of the need to satisfy certain regulatory requirements and obtain marketing authorisation before medicinal products (both human and veterinary) and plant protection products (such as pesticides or insecticides) can be placed on the market.

In order to satisfy the regulatory requirements for a new medicinal product, pre-clinical studies and clinical trials normally have to be carried out, in order to demonstrate the safety, efficacy and quality of the product. This can take a number of years (around 12 on average). It was recognised that the effect of these mandatory requirements would reduce the period of exclusive exploitation under a patent to just eight years, placing the European life sciences industry at a significant disadvantage compared with the US and Japan, where pharmaceutical patent term extensions have been available since the 1980s. So supplementary protection certificates (SPCs) were introduced in Europe to compensate, at least in part, for the investment made in these areas of life science research.

Article 63 EPC

Term of the European patent

(1) The term of the European patent shall be 20 years from the date of filing of the application.

(2) Nothing in the preceding paragraph shall limit the right of a Contracting State to extend the term of a European patent, or to grant corresponding protection which follows immediately on expiry of the term of the patent, under the same conditions as those applying to national patents:

[...]

(b) if the subject-matter of the European patent is a product or a process for manufacturing a product or a use of a product which has to undergo an administrative authorisation procedure required by law before it can be put on the market in that State.

In a communication of 28 October 2016 entitled "Upgrading the Single Market: More opportunities for people and business", the European Commission announced that it would explore the re-calibration of certain aspects of SPC protection following a review of the impact of the current system on the European pharmaceutical sector.

Legal framework – SPCs

Medicinal products – SPC Regulation

One of the key objectives of the legislature was to provide a uniform solution at Community level, thereby preventing the heterogeneous development of national laws which might affect the functioning of the internal market. Council Regulation (EEC) No. 1768/92 of 18 June 1992 concerning SPCs for medicinal products entered into force on 2 January 1993. It was subsequently amended and later codified and repealed by Regulation (EC) No. 469/2009 (**Medicinal SPC Regulation**), which entered into force across the European Union on 6 July 2009.

Iceland, Liechtenstein, Norway and Switzerland are members of the European Free Trade Association (EFTA) and are not bound by the Medicinal SPC Regulation. Instead, they are covered by Regulation (EEC) 1768/92, which entered into force (with certain amendments) on 1 July 1994 in those EFTA states which were a party to the European Economic Area Agreement (EEA Agreement).

Plant protection products – SPC Regulation

Regulation (EC) No. 1610/96 creating an SPC for plant protection products (**Plant SPC Regulation**) entered into force on 8 February 1997. Generally speaking, the Plant and Medicinal SPC Regulations contain broadly similar provisions. However, there are differences, some of which are highlighted below. It is also important to note that the Medicinal SPC Regulation is to be read and interpreted in the light of the following sections of the Plant SPC Regulation, since recital (17) Plant SPC Regulation states that:

Together, the Medicinal SPC Regulation and Plant SPC Regulation are referred to in this publication as the **SPC Regulations**.

"(17) Whereas the detailed rules in recitals 12, 13 and 14 and in Articles 3 (2), 4, 8 (1) (c) and 17 (2) of this Regulation are also valid, mutatis mutandis, for the interpretation in particular of recital 9 and Articles 3, 4, 8 (1) (c) and 17 of Council Regulation (EEC) No 1768/92."

Explanatory Memorandum

Although it does not have binding effect, the **Explanatory Memorandum** to the proposal for Council Regulation (EEC) of 11 April 1990 (COM(90) 101 final) concerning the creation of a supplementary protection certificate for medicinal products is frequently referred to by the national patent offices, national courts and the Court of Justice of the European Union (**CJEU**) as a guide to the interpretation of the SPC Regulations.

The CJEU was formerly known as the European Court of Justice (ECJ). These two terms are used interchangeably in this module.

Medicinal SPC Regulation

Key definitions

→ Certificates

SPCs (or certificates, as they are referred to in the legislation) are the mechanism by which industry is compensated, at least in part, for the erosion of the period of exclusivity under a patent as a result of the time which elapses between the filing of the patent application and the grant of marketing authorisation to place the product on the market.

SPCs are not strictly patent term extensions, but rather separate (or *sui generis*) rights that come into effect upon expiry of a patent for a maximum period of five years, which can themselves be extended if the criteria for a six-month paediatric extension are satisfied (see below).

SPC protection confers the same rights and obligations as the basic patent (the patent designated by the SPC applicant as the basis of its application). However, unlike the basic patent, an SPC does not extend the protection conferred across the entire scope of the patent claims, but will only protect the product covered by the authorisation to place the corresponding medicinal product (or plant protection product) on the market, and any use of that product as a medicinal product (or plant protection product) that has been authorised before expiry of the SPC.

Article 1(d) Medicinal SPC Regulation
'Certificate' means the supplementary protection certificate.

→ See Articles 4 and 5 Medicinal SPC Regulation and recital (10).

→ Article 1(a) – Medicinal product

Both SPC Regulations distinguish between the terms “medicinal product” and “plant protection product” on the one hand and “product” on the other. The definition of the former is based on the early regulatory directives which prescribed the requisite studies and trials that needed to be conducted in order to bring a medicinal product to the market, and referred to the restoration, correction or modification of physiological functions in humans or animals. It is the medicinal product that is the subject of the regulatory authorisations referred to in Article 3 (see below).

Article 1(a) Medicinal SPC Regulation
'Medicinal product' means any substance or combination of substances presented for treating or preventing disease in human beings or animals and any substance or combination of substances which may be administered to human beings or animals with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in humans or in animals.

→ Article 1(b) – Product

The term “product” is defined as the “**active ingredient** or combination of active ingredients of a medicinal product”. However, the term “active ingredient” is itself not defined in the Medicinal SPC Regulation, and its meaning has been the subject of a number of disputes that have resulted in preliminary rulings from the CJEU.

Article 1(b) Medicinal SPC Regulation
'Product' means the active ingredient or combination of active ingredients of a medicinal product.

→ See below for more information on the SPC application and examination process and an overview of preliminary rulings of the CJEU.

The CJEU confirmed its approach in C-210/13 *GlaxoSmithKline Biologicals v Comptroller-General of Patents (GSK)*. This case concerned two SPC applications relating to an adjuvant used in combination with a particular influenza vaccine. The case turned on whether the adjuvant was an active ingredient and therefore capable of satisfying the “product” definition in the Medicinal SPC Regulation. With reference to its earlier judgment in C-431/04 *Massachusetts Institute of Technology (MIT)* and to the Explanatory Memorandum, the CJEU confirmed that the term “product” is to be understood as meaning an active substance in the strict sense. Accordingly, “a substance which does not have any **therapeutic effect of its own** and is used to obtain a certain pharmaceutical form of a medicinal product is not covered by the concept of ‘active ingredient’, which, in turn, is used to define the term ‘product’.”

→ See *MIT*, sections 19, 21, 25–28; *GSK*, sections 29–35.

In reaching this conclusion, the CJEU recognised that it is not unusual for a substance which does not have therapeutic effects of its own to *influence* the therapeutic efficacy of the active ingredient of a medicinal product.

In C-202/05 *Yissum Research and Development Company of the Hebrew University of Jerusalem v Comptroller-General of Patents (Yissum)*, the CJEU relied *inter alia* on the finding in *MIT* that the concept of “product” in Article 1(b) must be interpreted strictly. The CJEU extended this to mean that the concept of “product” **cannot include the therapeutic use** of an active ingredient.

The CJEU also cited *Pharmacia*, described in more detail under Article 13.

→ See below for more information on the impact of this decision on compliance with Article 3(d).

In C-631/13 *Forsgren v Österreichisches Patentamt*, questions were referred to the CJEU to ascertain whether an SPC could be granted for an active ingredient (protein D) that is covalently bonded to other active ingredients in the medicinal product but nonetheless retains its own therapeutic effect. The CJEU observed that a substance is considered to be an active ingredient under Article 1(a) when it has an independent pharmacological, immunological or metabolic effect, regardless of whether it is bound to another active ingredient. However, Article 3(b) precludes the grant of an SPC for an active ingredient whose effect does not fall within the therapeutic indication covered by the relevant marketing authorisation.

→ See also the *Bayer* case concerning the meaning of “active substances” in the context of plant protection products.

→ Article 1(c) – Basic patent

SPCs are granted in respect of a basic patent, which is a patent which protects:

- (a) a product as such,
- (b) a process to obtain a product, or
- (c) an application of a product.

The basic patent can be either a national patent or a European patent designating the member state in which the SPC application is lodged.

Article 1(c) Medicinal SPC Regulation

“Basic patent” means a patent which protects a product as such, a process to obtain a product or an application of a product, and which is designated by its holder for the purpose of the procedure for grant of a certificate.

Whilst the unitary patent will be capable of being a basic patent for the purposes of Article 1(c), individual national applications will have to be made in the same way as for existing European patents. There is currently no available mechanism for the grant of a single, unitary SPC.

Overview of the SPC examination process

The SPC Regulations are intended to provide a Community-wide solution and have direct effect across the member states of the EU. However, whilst SPCs are examined on the basis of the same conditions, as prescribed by the SPC Regulations, they are granted by the competent intellectual property offices of individual member states and have effect only in those member states in which they are granted.

This has in the past led to divergent approaches being adopted across Europe as to how the SPC Regulations should be applied in practice. If a dispute arises between an applicant and the national patent office and either party appeals, the relevant national court can (and frequently does) refer questions of interpretation to the CJEU, seeking a preliminary ruling on a point of interpretation for the national court to apply to the particular facts of that case.

Some national patent offices conduct a substantive examination of SPC applications, while the procedure in other jurisdictions is closer to a formalities examination.

Under Article 267 Treaty on the Functioning of the European Union, the court may request a preliminary ruling from the CJEU if it considers that a decision on the question is “necessary” to enable it to give judgment.

Questions of interpretation arising from any of the EFTA states are referred to the EFTA Court for a preliminary ruling or “advisory opinion” on the basis of a very similar procedure.

Overview of the SPC application process

Generally speaking, SPC applications should be lodged with the competent intellectual property office of the member state which granted the basic patent and in which the authorisation referred to in **Article 3(b)** was obtained (see **Article 9 Medicinal SPC Regulation**).

Under **Article 7**, the general rule is that applications for SPCs must be lodged within **six months** of either:

- (a) the date on which the **marketing authorisation** to place the product on the market was granted in the member state in which the application was filed, or
- (b) the date on which the **basic patent** was granted (if later).

Article 19 Regulation (EEC) No. 1768/92 (now repealed) previously provided for exceptions to this general rule in the form of transitional provisions. Article 19 is not considered further in this module, except to note that certain case law concerning Article 19 is relevant to the assessment of SPC duration and is covered under Article 13 below.

Article 8 Medicinal SPC Regulation sets out the content of the SPC application, which is based on limited documentation and objective criteria that are, in principle, easy to verify, consistent with the objective of providing a “simple, transparent system”. These requirements include:

- (a) the number of the basic patent;
- (b) a copy of the authorisation to place the product on the market as referred to in Article 3(b), i.e. in the **member state** in which the SPC application is lodged (see right-hand column and below); and
- (c) if the authorisation in (b) above is not the first authorisation to place the product on the market as a medicinal product in the **Community**, the number and date of that authorisation.

Where the authorisation referred to in (b) above is held by a different entity to the patentee/SPC applicant (e.g. a licensee), and the SPC applicant is unable to provide a copy, the ECJ held in C-181/95 *Biogen v SmithKline Beecham Biologicals (Biogen)* that the application must not be refused on that ground alone. The ECJ recognised that, by simple co-operation, the national authority granting the SPC can itself obtain a copy of the authorisation from the relevant authority which issued it.

Article 9 Medicinal SPC Regulation

(1) The application for a certificate shall be lodged with the competent industrial property office of the Member State which granted the basic patent or on whose behalf it was granted and in which the authorisation referred to in Article 3(b) to place the product on the market was obtained, unless the Member State designates another authority for the purpose.

Article 7(1) and (2) Medicinal SPC Regulation

1. The application for a certificate shall be lodged within six months of the date on which the authorisation referred to in Article 3(b) to place the product on the market as a medicinal product was granted.

2. Notwithstanding paragraph 1, where the authorisation to place the product on the market is granted before the basic patent is granted, the application for a certificate shall be lodged within six months of the date on which the patent is granted.

Article 19 Regulation (EEC) No. 1768/92

Any product which, on the date on which this Regulation enters into force, is protected by a valid basic patent and for which the first authorisation to place it on the market as a medicinal product in the Community was obtained after 1 January 1985 may be granted a certificate.

In the case of certificates to be granted in Denmark and in Germany, the date of 1 January 1985 shall be replaced by that of 1 January 1988.

In the case of certificates to be granted in Belgium and in Italy, the date of 1 January 1985 shall be replaced by that of 1 January 1982.

→ See section 16 Explanatory Memorandum on the provision of a “simple, transparent system”.

Article 3(b) Medicinal SPC Regulation

A certificate shall be granted if, in the Member State in which the application referred to in Article 7 is submitted and at the date of that application:
[...]

(b) A valid authorisation to place the product on the market as a medicinal product has been granted in accordance with Directive 2001/82/EC or Directive 2001/83/EC.

Legal requirements

→ Article 2 – Scope of the Regulation

According to Article 2 Medicinal SPC Regulation (and subject to it satisfying the other terms and conditions for obtaining a certificate), any product that satisfies the following criteria may be the subject of a certificate:

- (a) the product is protected by a patent; and
- (b) the product was subject to an administrative authorisation procedure as laid down in Directive 2001/83/EC (concerning medicinal products for human use) or Directive 2001/82/EC (concerning medicinal products for veterinary use) *prior to* being placed on the market as a medicinal product.

As previously mentioned, the purpose of these directives is to ensure the quality, safety and efficacy of medicinal products for the protection of public health across the EU. As well as national authorisations obtained in accordance with the requirements of these directives, Regulation (EC) No. 726/2004 provides a separate mechanism for obtaining centralised marketing authorisations which are granted by the European Commission following a positive opinion of the European Medicines Agency (EMA). These centralised authorisations proceed to grant simultaneously across all member states of the European Union. Both national and centralised authorisations may form the basis of an SPC application.

In C-195/09 *Synthon v Merz Pharma* (confirmed in C-427/09 *Generics v Synapttech*), the CJEU decided that the relevant territory for interpreting the meaning of the term “market” in Article 2 is the **European Community** market rather than the market of a member state. Further, the CJEU held that a product which was placed on the market in the European Community as a medicinal product before obtaining a marketing authorisation in accordance with Directive 2001/83/EC (then Directive 65/65/EEC) and, in particular, without undergoing safety and efficacy testing, is not within the scope of the Medicinal SPC Regulation.

The CJEU also ruled that any SPC granted for a product which falls outside the scope of the Medicinal SPC Regulation is **invalid**, notwithstanding the fact that Article 2 is not one of the grounds of invalidity listed in **Article 15**.

Article 2 Medicinal SPC Regulation

Any product protected by a patent in the territory of a Member State and subject, prior to being placed on the market as a medicinal product, to an administrative authorisation procedure as laid down in [Directive 2001/83/EC] or [Directive 2001/82/EC] may, under the terms and conditions provided for in this Regulation, be the subject of a certificate

Directive 2001/83/EC

of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for **human** use

Directive 2001/82/EC

of the European Parliament and of the Council of 6 November 2001 on the Community code relating to **veterinary** medicinal products

Article 15 Medicinal SPC Regulation

1. The certificate shall be invalid if:

- (a) it was granted contrary to Art 3;
- (b) the basic patent has lapsed before its lawful term expires;
- (c) the basic patent is revoked or limited to the extent that the product for which the certificate was granted would no longer be protected by the claims of the basic patent or, after the basic patent has expired, grounds for revocation exist which would have justified such revocation or limitation.

→ Article 3 – Conditions for obtaining a certificate

According to Article 3 Medicinal SPC Regulation, an SPC is to be granted if, in the **member state in which the application is submitted**, and at the date of that application, each of the following conditions are satisfied:

- (a) the product is protected by a basic patent in force;
- (b) a valid authorisation to place the product on the market as a medicinal product has been granted in accordance with Directive 2001/82/EC (concerning veterinary medicinal products) or Directive 2001/83/EC (concerning products for human use);
- (c) the product has not already been the subject of a certificate; and
- (d) the authorisation referred to in point (b) is the first authorisation to place the product on the market as a medicinal product.

→ Article 3(a)

To satisfy Article 3(a) it is necessary to fulfil two requirements. First, there must be a basic patent that is still in force at the time the SPC application is filed in the member state in which the SPC application is submitted. Second, the product must be protected by that basic patent. There is no definition of “protected by” in the Medicinal SPC Regulation itself, and it is this limb of the test that has resulted in litigation before the national courts and multiple references to the CJEU for preliminary rulings on questions of interpretation of the SPC Regulation.

In *C-392/97 Farmitalia*, heard in 1999, the CJEU held that whether a product is protected by a basic patent under Article 3(a) is to be determined under national rules governing the basic patent. However, it was unclear what those national rules should be, and two divergent approaches began to emerge across Europe, particularly in the context of cases concerning combination products. These were:

- (1) the disclosure test (also referred to in some member states as the “clear pointer” or “subject-matter” test); and
- (2) the infringement-type test.

As a consequence of the lack of harmonisation in the interpretation of the SPC Regulation, the CJEU was asked to consider the meaning of Article 3(a) (and 3(b)) in *C-322/10 Medeva v Comptroller General of Patents (Medeva)*, which concerned combination products. Consistent with the opinion of the Advocate-General, the CJEU adopted a strict approach to Article 3(a), ruling that it must be interpreted as precluding the grant of an SPC “relating to active ingredients of the authorised product which are **not specified** in the wording of the claims of the basic patent”. The *Medeva* case is considered further below.

Article 3(a) Medicinal SPC Regulation

The product is protected by a basic patent in force.

The UK Court of Appeal, which referred the questions and gave judgment applying the CJEU’s ruling, observed that, whilst the judgment of the CJEU makes no reference to the opinion of the Advocate-General, it is consistent with the observations set out in its opinion (see *Medeva v Comptroller General of Patents* [2012] EWCA Civ 523 at section 21).

In other combination cases (C-518/10 *Yeda Research and Development Company v Comptroller General of Patents (Yeda)*; C-6/11 *Daiichi v Comptroller General of Patents (Daiichi)*; C-630/10 *Queensland v Comptroller General of Patents (Queensland)*), the CJEU reached very similar decisions by reasoned order, referring to the need for active ingredients to be “**identified**” rather than “specified” in the wording of the claims in order to be eligible for the grant of an SPC. Neither the CJEU nor the national courts seem to have drawn a material distinction between these two terms.

In *Yeda*, the claims were all directed to a combination product (A+B), but the authorised medicinal product had been construed by the UK Patents Court as a single active ingredient (A). The CJEU held in that case that Article 3(a) precluded the grant of a SPC where the active ingredient, even though itself identified in the wording of the claims of the basic patent as part of a combination, is not the subject of any claim to that active ingredient alone.

In the context of the product-by-process claim at issue in *Queensland*, the CJEU held that Article 3(a) precluded the grant of an SPC for a product other than that identified in the wording of the claims of the patent as the product deriving from that process. However, whether it is possible to obtain the product *directly* as a result of that process was held to be irrelevant.

Although in *Medeva* the UK Court of Appeal (the referring court subsequently tasked with applying the CJEU’s ruling) interpreted the judgment as a rejection of the infringement-type test, there nonetheless remained uncertainty as to what “specified” or “identified” was intended to mean, in particular in non-combination cases.

Following a further referral to the CJEU in C-493/12 *Eli Lilly and Company v Human Genome Sciences*, this time in the context of a single active ingredient rather than a combination product, and a basic patent claiming a class of monoclonal antibodies defined in functional rather than structural terms, the CJEU held that it is not necessary for the active ingredient to be identified in the claims of the basic patent by a structural formula. However, where the active ingredient is covered by a functional formula in the claims, it must be possible to conclude on the basis of those claims, interpreted *inter alia* in the light of the description of the invention, as required by Article 69 EPC and the Protocol on its interpretation, that “... the claims relate, implicitly but necessarily and specifically, to the active ingredient in question ...”.

The CJEU observed that this is a matter for the referring national (UK) court, which subsequently held that the CJEU’s decision requires the application of the relevant rules (i.e. Article 69 EPC or Section 125 UK

Where a question referred to the CJEU is identical to a question on which the CJEU has already been called on to rule, or where the answer to the question admits of no reasonable doubt or may be clearly deduced from existing case law, the CJEU may give its decision by reasoned order rather than a full judgment, as was the case in *Daiichi, Queensland and Yeda* (see Article 99 Rules of Procedure of the CJEU of 25 September 2012, as amended on 18 June 2013 (OJ L 173, 26.6.2013)).

Antibody claims defined in **functional** terms are generally defined by reference to their ability to bind to a particular target antigen.

Antibody claims defined in **structural** terms are generally defined by reference to the amino acid sequence of the antibody itself and/or the sequence of the target antigen to which the antibodies bind.

Patents Act 1977) to ascertain the extent of the invention, and that HGS's claim, to an antibody which binds specifically to a novel antigen, satisfied Article 3(a).

→ Article 3(b)

As reflected under Article 2 above, Article 3(b) states that a valid authorisation must have been granted to place the product on the market in the member state in which the SPC application is submitted, i.e. an authorisation in accordance with Directive 2001/83/EC or Directive 2001/82/EC.

In *Medeva*, the Advocate-General recognised that a strict approach to Article 3(a) (see above) should be balanced with a more purposive or teleological approach to Article 3(b).

Therefore, Article 3(b) does not preclude the grant of an SPC for a combination of active ingredients that are specified in the wording of the claims (and so satisfy Article 3(a)) in circumstances where the medicinal product which is the subject of the marketing authorisation contains not only those active ingredients but also additional active ingredients.

The CJEU reached the same conclusion in C-422/10 *Georgetown University v Comptroller General of Patents (Georgetown I)*.

Article 3(b) Medicinal SPC Regulation

A certificate shall be granted if, in the Member State in which the application referred to in Article 7 is submitted and at the date of that application:
[...]

(b) a valid authorisation to place the product on the market as a medicinal product has been granted in accordance with Directive 2001/82/EC or Directive 2001/83/EC, as appropriate.

Georgetown I was joined with *Medeva* for the purposes of the oral procedure, but separate judgments were given. Both judgments were handed down on 24 November 2011.

→ Practical guidance on satisfying Article 3(a) and (b) in combination product cases

For multi-component vaccines, such as those at issue in *Medeva* and *Georgetown I*, the medicinal product authorised to be placed on the market (e.g. with active ingredients A+B+C+D+E) often comprises more active ingredients than are claimed in the patent (e.g. A+B only). There is therefore a mismatch between the patented product under Article 3(a) and the authorised product under Article 3(b). However, the effect of the CJEU's combined reasoning on Article 3(a) and (b) means that SPCs can nonetheless be granted on the basis of an application for A+B alone. By contrast, an SPC application filed for A+B+C+D+E would satisfy Article 3(b) but fail under Article 3(a).

This interpretation was confirmed in C-443/12, *Actavis Group PTC EHF and Actavis UK Ltd v Sanofi*
→ see under Article 3(c) below

In this example, A+B are specified/identified in the wording of the claims in accordance with Article 3(a), and Article 3(b) does not prohibit the grant of an SPC based on an MA which authorises a product to be placed on the market comprising more active ingredients than are specified/identified in the claim (e.g. C+D+E).

However, there appears to be no solution where the claims are directed to more active ingredients than the authorised medicinal product. Following *Yeda*, where the claims are directed to A+B but the MA authorises A only, an SPC application based on A alone will fail under Article 3(a).

→ Article 3(c)

Broadly speaking, this provision is intended to ensure that only one SPC may be granted for any given product. The underlying rationale is explained in the Explanatory Memorandum, i.e. that a product is understood to mean an “**active substance in the strict sense**”, such that minor changes, such as a new dose or a different salt or ester or pharmaceutical form, will not lead to the issue of a new SPC. However, the CJEU has confirmed that there are circumstances in which more than one SPC may be granted per product.

First, where a product is protected by a number of basic patents which belong to different patent holders (e.g. a patent which protects the product *per se*, the process for making the product or a therapeutic use of the product), Article 3(c) permits SPCs to be granted to each of those patentees, providing the other conditions for grant are satisfied (see *Biogen* and Case C-482/07 *AHP Manufacturing (AHP)*, citing Article 3(2) Plant SPC Regulation, which applies equally to the interpretation of Article 3 Medicinal SPC Regulation).

Secondly, the form of wording used by the CJEU (and later referred to in *Medeva*) casts doubt on whether a patentee is entitled to one SPC *per product* per basic patent (as was previously understood by many national patent offices and practitioners) or whether only one SPC per patent was permitted, irrespective of the number of different products protected by a particular basic patent. This issue was recently resolved in C-484/12 *Georgetown University v Octrooicentrum Nederland (Georgetown II)* and C-443/12 *Actavis Group v Sanofi (Actavis)*, in which the CJEU confirmed that multiple SPCs can be obtained on the basis of the same basic patent, provided that each of the products in respect of which an SPC is sought is protected as such by the basic patent within the meaning of Article 3(a).

On the facts in *Georgetown II*, the patentee already had an SPC for a combination of active ingredients, but was entitled to obtain a further SPC for one of those active ingredients alone (which, individually, was also protected as such by the patent under Article 3(a)). It was recognised in *Georgetown II* that, even if the protection conferred by the two SPCs were to overlap, they would, in principle, expire on the same date, because the relevant marketing authorisation was the same (see section 35 of *Georgetown II* and the section below on Article 13), so the avoidance of evergreening was not a concern.

A different conclusion was reached in *Actavis*. Sanofi already had an SPC for a single active ingredient and sought to enforce a second (later) SPC for a combination product which included the same single active as the first SPC. The CJEU referred to the “inventive advance” of the basic patent and held that it would be unacceptable for a patentee to obtain a new

Article 3(c) Medicinal SPC Regulation

The product has not already been the subject of a certificate.

→ See the definition of “product” in Article 1(b) and e.g. section 11 of the Explanatory Memorandum.

Article 3 Plant SPC Regulation

2. The holder of more than one patent for the same product shall not be granted more than one certificate for that product. However, where two or more applications concerning the same product and emanating from two or more holders of different patents are pending, one certificate for this product may be issued to each of these holders.

Recital (17) Plant SPC Regulation indicates that Article 3 Medicinal SPC Regulation is to be interpreted in the light of the above provision.

The CJEU in *Medeva* stated at section 41 that “...where a patent protects a product ... only one certificate may be granted for that basic patent (see *Biogen*, section 28).”

Georgetown II and *Actavis* were heard together before the CJEU on 12 September 2013 and judgment was handed down on the same day (12 December 2013).

Before the CJEU delivered its rulings in *Georgetown II* and *Actavis*, Arnold J of the UK Patents Court held (*obiter dictum*, as the point was not in issue) that two SPCs could be granted based on the same basic patent because they are for different products. See *University of Queensland v Comptroller-General of Patents* [2012] EWHC 223 (Pat) following the reference to the CJEU in *Queensland*.

The CJEU also acknowledged that a different outcome on the Article 3(c) issue could give rise to “circumvention tactics”, such as the filing of divisional patents to confer separate protection on each product.

The CJEU declined to rule on the Article 3(a) point referred in *Actavis* in view of the answer given to the Article 3(c) question, which the CJEU regarded as determinative of the issue.

SPC, potentially for a longer period of protection, each time he places on the market a medicinal product containing the core inventive advance of that product and another active ingredient which is not protected as such by that patent.

The CJEU reaffirmed this position in C-577/13 *Actavis v Boehringer*, holding that once an SPC has been obtained on a basic patent claiming a “mono” product, the holder is precluded from obtaining a second certificate on a claim to a combination product containing the same active ingredient.

→ Article 3(d)

This provision is intended to ensure that the authorisation to place the product on the market in the member state in which the application is lodged is the first such authorisation. Much of the case law that has developed turns on establishing the correct product under Article 1(b).

In *Yissum*, the ECJ held that the concept of “product” in Article 1(b) must be interpreted strictly and cannot include the therapeutic use of an active ingredient. Therefore, in a case where a basic patent relied upon protects a second medical use of an active ingredient, that use does not form an integral part of the definition of the product. Consequently, the SPC application was denied because the active ingredient had already been granted an authorisation to be placed on the market in respect of the first use, such that the authorisation included in the application was not the first for the purposes of satisfying Article 3(d).

The CJEU has considered Article 3(d) more recently in 2012 in C-130/11 *Neurim Pharmaceuticals v Comptroller-General of Patents (Neurim)*. In this case, Neurim had applied for an SPC for melatonin (a natural hormone) based on a basic patent covering the use of appropriate formulations of melatonin for human use in treating insomnia, and a marketing authorisation covering such use. Neurim’s SPC application was rejected because of a prior third-party authorisation for the use of melatonin in regulating the seasonal breeding activity of sheep, such that Neurim’s marketing authorisation was not considered to be the first to place melatonin on the market as a medicinal product under Article 3(d).

Neurim’s position was that the first marketing authorisation for the purposes of Article 3(d) is the first marketing authorisation that falls within the scope of the basic patent. In this case, the earlier marketing authorisation for the use of melatonin in regulating the seasonal breeding activity of sheep was not a use that would fall within the scope of Neurim’s patent, so should be ignored.

Article 3(d) Medicinal SPC Regulation

The valid authorisation in point (b) is the first authorisation to place the product on the market as a medicinal product.

→ See under Article 1(b) above for more background information on the key CJEU decisions, including *MIT*, *Yissum*, *GSK* and *Forsgren*.

The UK Intellectual Property Office had rejected Neurim’s application, relying *inter alia* on the CJEU’s earlier preliminary rulings in *Yissum*, *MIT* and *Pharmacia*.

The CJEU agreed with *Neurim*, ruling that Articles 3 and 4 are to be interpreted as meaning that the mere existence of an earlier marketing authorisation obtained for a veterinary medicinal product does not preclude the grant of an SPC for a *different application* of the same product for which a marketing authorisation has been granted, provided that the application is within the limits of the protection conferred by the basic patent.

It remains unclear how widely the CJEU's judgment in *Neurim* will be interpreted by the national patent offices and courts, particularly on different facts (although the CJEU has already adopted a narrow application of *Neurim* in other contexts – see its subsequent decisions in *GlaxoSmithKline* (above) and *AstraZeneca* (below)). However, the CJEU's reasoning in sections 25 and 26 of *Neurim* nonetheless suggests that it should be irrelevant whether the earlier use is veterinary or human and whether or not it is protected by an earlier patent (on the facts in *Neurim*, melatonin was not protected as such by an earlier patent).

Importantly, the CJEU confirmed in *Neurim* that the protection conferred by the SPC will not cover the active ingredient as such, but only the new use of that product (*see below on Articles 4 and 5*).

The section on Article 13 below also discusses what is meant by the “first marketing authorisation” in the context of the “first authorisation to place the product on the market in the Community” for the purposes of calculating SPC duration.

Neurim

"25. Therefore, if a patent protects a therapeutic application of a known active ingredient which has already been marketed as a medicinal product, for **veterinary or human use**, for other therapeutic indications, **whether or not protected by an earlier patent**, the placement on the market of a new medicinal product commercially exploiting the new therapeutic application of the same active ingredient, as protected by the new patent, may enable its proprietor to obtain an SPC, the scope of which, in any event, could cover, not the active ingredient, but only the new use of that product.

26. In such a situation, only the MA of the first medicinal product, comprising the product and authorised for a therapeutic use corresponding to that protected by the patent relied upon for the purposes of the application for the SPC, may be considered to be the first MA of 'that product' as a medicinal product exploiting that new use within the meaning of Article 3(d) of the SPC Regulation."

In January 2016, in decision 34R104/15, the Higher Regional Court of Vienna followed *Neurim* and confirmed that an SPC application could be filed on the basis of a type II variation of an existing MA (for a new indication of Botox, protected by a second medical use patent) as a “first authorisation” under Article 3(d).

→ Articles 4 and 5 – Scope of protection

According to **Article 5**, an SPC confers the same rights as conferred by the basic patent and is subject to the same limitations and obligations.

However, this is subject to the provisions of **Article 4**, which states that the scope of protection conferred by an SPC extends only to the product authorised to be placed on the market (and for any use of the product as a medicinal product that has been authorised before expiry of the SPC), rather than extending the protection conferred by a basic patent in its entirety.

In C-442/11 *Novartis v Actavis UK (Novartis)*, the CJEU confirmed that, once granted, SPCs confer patent-like protection. Where a product comprising a single active ingredient (A) is protected by a basic patent, and if during the lifetime of a basic patent concerning A the patentee was entitled to oppose the marketing of a medicinal product containing A in combination with one or more other active ingredients (e.g. A+B), then the SPC similarly confers the same rights to oppose the marketing of a medicinal product containing A in combination with other active ingredients.

This rationale appeared to be an integral part of the reasoning on Article 3(b) in *Medeva* and *Georgetown I* etc., as this approach allows the grant of an SPC for A based on a patent which protects A and a marketing authorisation for a product comprising A+B+C, etc. to be enforceable under Articles 4 and 5 against the third-party marketing of:

- A or
- A+B or
- A+B+C, and so on

In C-392/97 *Farmitalia*, a case involving a small molecule active ingredient, the CJEU held that an SPC is capable of covering the product, as a medicinal product, in any of the forms enjoying the protection of the basic patent. Accordingly, “the certificate is capable of covering the active ingredient as such and also its various derived forms such as salts and esters”.

→ Articles 6 to 8 and so-called third-party SPCs

Article 6 states that the certificate is to be granted to the holder of the basic patent or his successor in title, but Articles 7 and 8 (concerning the SPC application itself) do not prescribe who the SPC applicant must be. Consequently, questions have arisen concerning entitlement to SPCs in circumstances where the patentee and the marketing authorisation holder are not the same entity.

Article 4 Medicinal SPC Regulation

Within the limits of the protection conferred by the basic patent, the protection conferred by a certificate shall extend only to the product covered by the authorisation to place the corresponding medicinal product on the market and for any use of the product as a medicinal product that has been authorised before the expiry of the certificate.

This provision is to be interpreted in the light of Article 4 Plant SPC Regulation, which is identical other than referring to “authorisations” (plural) to place the corresponding relevant product on the market.

Article 5 Medicinal SPC Regulation

Subject to the provisions of Article 4, the certificate shall confer the same rights as conferred by the basic patent and shall be subject to the same limitations and the same obligations.

See also recital (10), which states: “...
The protection granted shall furthermore be strictly confined to the product which obtained authorisation to be placed on the market as a medicinal product.”

The CJEU’s decision in *Novartis* was made by reasoned order with reference to the *Medeva* line of cases (see Article 3(a) and (b) above), since its consideration of the correct interpretation of Articles 4 and 5 was an integral part of its reasoning in respect of Article 3(a) and (b).

This rationale is also reflected in the later CJEU judgments in *Actavis* (see section 35) and *Georgetown II* (see section 39).

In *Pharma v Intervet*, a case referred from the Oslo District Court, the EFTA court apparently approved the reasoning of *Farmitalia* in the context of complex biological products such as the vaccine composition at issue in that case, suggesting that medicinal products that are “therapeutically equivalent” would fall within the scope of a certificate under Article 4. However, the EFTA court also concluded that an SPC would be invalid “to the extent it is granted a wider scope than that set out in the relevant marketing authorisation”.

The CJEU in *Biogen* (as later confirmed in *AHP*) held that, where a medicinal product is covered by several basic patents which belong to a number of different patent holders, the SPC Regulation seeks to confer supplementary protection without instituting any preferential ranking amongst the patentees according to their relative contribution towards bringing the product to market. The SPC Regulation does not therefore preclude the grant of an SPC to each patentee (in circumstances where only one of them will be the marketing authorisation holder).

In the UK, in *Eli Lilly v Human Genome Sciences, Inc.* [2012] EWHC 2290 (Pat), Warren J held (at first instance) that the holder of a basic patent can make an application for an SPC “in reliance on a marketing authorisation granted to a third party having **no connection of any sort** with that holder”.

However, under Article 3(c) only one SPC may be granted per basic patent (see above).

The CJEU in *AHP* also confirmed that it is not a requirement that, notwithstanding the wording of recital (17) and Article 3(2) Plant SPC Regulation, the earlier SPC applications remain *pending* whilst the later application(s) is/are lodged.

See section 62 of this judgment of Warren J. However, whilst Warren J subsequently referred to this as his “clear view”, he emphasised that he had not found the matter to be *acte clair* (see *Eli Lilly v Human Genome Sciences, Inc.* [2012] EWHC 2857 (Pat) at section 21).

→ Article 13(1) and (2) – Duration of the certificate

When calculating the duration of an SPC, the Regulation establishes a system that reflects the time taken for the patentee to obtain the first authorisation to put the product on the EU/EEA market.

STEP 1: Supplementary protection granted is equal to the period which elapsed between the filing date of the basic patent application and the date of the first authorisation in the EU/EEA, reduced by a period of five years, as follows:

$$(A - B) - 5 \text{ years} = \text{SPC duration}$$

A = First marketing authorisation in the EU/EEA

B = Filing date of the basic patent application

Article 13 Medicinal SPC Regulation

(1) The certificate shall take effect at the end of the lawful term of the basic patent for a period equal to the period which elapsed between the date on which the application for a basic patent was lodged and the date of the **first authorisation to place the product on the market in the Community**, reduced by a period of five years.

(2) Notwithstanding paragraph 1, the duration of the certificate may not exceed five years from the date on which it takes effect.

In C-471/14 *Seattle Genetics*, the CJEU confirmed that the term of an SPC is to be calculated from **the date of notification** of the first marketing authorisation.

STEP 2: The total period of supplementary protection under an SPC is also subject to a **maximum duration of five years**. Therefore, even if the time taken to obtain the first MA after the patent application was filed was ten years or more, the SPC duration will nonetheless be capped at five years. This ensures that the total period of exclusivity conferred collectively under the patent and the SPC does not exceed fifteen years.

This five-year maximum period of supplementary protection and the fifteen-year exclusivity cap from the time the medicinal product is first authorised to be placed on the market in the Community are reflected in recitals (9) and (10). The respective periods are said to provide “adequate effective protection” taking into account all the interests at stake, including those of public health.

If, on the other hand, the time taken to obtain regulatory approval is less than five years, it is not possible (subject to the availability of paediatric extensions – *see below*) for the patentee to obtain an SPC because he has already enjoyed fifteen years or more of exclusivity under the patent.

Compliance with Directives 2001/82 and 2001/83

In C-127/00 *Hässle v Ratiopharm (Hässle)*, the CJEU held that “the first marketing authorisation in the Community” refers only to a marketing authorisation granted in accordance with Directive 65/65 (now superseded by Directive 2001/83), even though there is no express reference to the Directive itself. Further, it was irrelevant whether the product could in fact be marketed, or whether further authorisations were required under national pricing and/or reimbursement legislation.

The CJEU also confirmed that Article 13 is not intended to take the place of the marketing authorisation referred to in Article 3(b) of the Medicinal SPC Regulation. Rather, it constitutes a further condition applying in circumstances where the latter (i.e. Article 3(b)) authorisation is not the first authorisation to place the product on the market as a medicinal product in the *Community* as well as the member state in which the application is submitted.

The CJEU also made an important general point of principle, deciding that the words “first marketing authorisation” must not be interpreted differently depending on the provision of the Medicinal SPC Regulation in which they appear. This is particularly true of the words “first authorisation ... to place ... on the market ... in the Community”.

Swiss marketing authorisations

Joined cases C-207/03 *Novartis & Others v Comptroller General of Patents* and C-252/03 *Ministre de l'économie v Millenium Pharmaceuticals (Novartis)* concerned the assessment of SPC duration based on a Swiss marketing authorisation. First, the CJEU confirmed that, in cases involving an EEA dimension, Article 13 is to be understood as referring to the first authorisation to place the product on the market in any territory covered by the EEA Agreement (i.e. not just the member states of the Community, as referred to in the Medicinal SPC Regulation).

Second, it established that a Swiss marketing authorisation is also capable of being the first marketing authorisation for the purposes of Article 13(1), even though Switzerland is not a member of either the Community or the EEA. This is because Swiss marketing authorisations were, at the relevant time, automatically recognised in Liechtenstein (which is a member of the EEA) pursuant to the regional union between the Swiss Confederation and the Principality of Liechtenstein.

Strictly speaking, *Hässle* concerned Article 19 (transitional provisions), although the same words appear in Article 13. The CJEU held in this case that they must not be interpreted differently depending on the provision in which they appear (see below).

Section 73 Hässle

73. At paragraph 24 of *Yamanouchi Pharmaceutical*, the Court held that the effect of Articles 8(1)(a)(iv) and (b), 9(2)(d) and 11(1)(d) of Regulation No 1768/92 is that the first marketing authorisation in the Community is not intended to take the place of the marketing authorisation provided for in Article 3(b) of the above-mentioned regulation, that is to say, the authorisation granted by the Member State in which the application is submitted; instead, it constitutes a further condition applying in the event that the latter authorisation is not the first authorisation to place the product on the market as a medicinal product in the Community.

Section 21 Pharmacia

21. Whilst noting that the term ‘first marketing authorisation in the Community’ must be interpreted in the same way in each of the provisions of the regulation in which it is used, it should be pointed out that, according to the sixth recital in its preamble, that regulation seeks to provide a uniform solution at Community level to the problem of inadequate patent protection, thereby preventing the heterogeneous development of national laws leading to further disparities which would be likely to create obstacles to the free movement of medicinal products within the Community.

However, an interpretation such as that proposed by *Pharmacia* would prevent the realisation of that objective. Under *Pharmacia*'s interpretation, the duration of the protection conferred by the certificate, calculated in accordance with Article 13 of the regulation, might be different for the same product.

These principles were recently confirmed in November 2013 in C-617/12 *AstraZeneca v Comptroller General of Patents (AstraZeneca)*. In particular, the CJEU emphasised that its judgment in *Neurim* was not intended to reflect a departure from its earlier decision in *Novartis*. In cases such as *AstraZeneca*, which involve an EEA dimension, an administrative authorisation granted by the Swiss regulatory authorities and automatically recognised in Liechtenstein must be regarded under Article 13(1) as the first authorisation to place the product on the market in the EEA.

Veterinary or human marketing authorisations

In C-31/03 *Pharmacia Italia, formerly Pharmacia & Upjohn (Pharmacia)*, the CJEU ruled that the grant of a marketing authorisation for a veterinary medicinal product in a particular member state precluded the grant of an SPC based on a later authorisation for the medicinal product in human use granted elsewhere in the Community. In other words, no distinction was made between authorisations for medicinal or veterinary use, so the first authorisation for veterinary use counted as the first marketing authorisation to place the product on the market in the Community. However, a similar issue was considered more recently in the second question referred in *Neurim*, and the answer given suggests a different outcome, depending on the nature of the patents in question. Consistent with the approach taken in respect of Article 3(b) in *Neurim*, the CJEU held that the relevant marketing authorisation for the purposes of assessing duration under Article 13(1) should be the authorisation of the product which is within the limits of protection conferred by the basic patent relied upon in the SPC application (not the earlier veterinary authorisation for the same product).

See section 72 *Hässle*.

72. In that connection, as stated in paragraph 57 of the present judgment, the words “first authorisation to place... on the market” must not be interpreted differently depending on the provision of Regulation No. 1768/92 in which they appear. The same is particularly true of the words ‘first authorisation to place... on the market ... in the Community’ (see, to that effect, *Yamanouchi Pharmaceutical*, cited above, paragraphs 23 and 24).

On 1 June 2005 the Swiss Confederation and the Principality of Liechtenstein abolished the automatic recognition mechanism. Now authorisations granted by the Swiss regulatory authorities are typically recognised after a 12-month period.

→ Article 13(3) – Six-month paediatric extensions and negative-term SPCs

The SPC Regulation was amended by Regulation (EC) No. 1901/2006 (**Paediatric Use Regulation**), which was intended to incentivise the study of the safety, efficacy and quality of medicinal products in paediatric patients. Consequently, Article 13(3) now allows for a further six-month extension of exclusivity for medicinal products in respect of which clinical trials have been conducted in accordance with an agreed paediatric investigation plan. This extension is available irrespective of whether the paediatric studies lead to the authorisation of a paediatric indication, provided that the results of those studies are reflected in the summary of product characteristics and, if appropriate, in the package leaflet of the relevant medicinal product (see Article 36(1) Paediatric Use Regulation).

Importantly, paediatric extensions apply only to products that are protected by an SPC or under a patent which qualifies for the granting of an SPC. Therefore if an SPC application is refused because the duration would result in one of negative or zero duration, the patentee would not be entitled to obtain a paediatric extension either, which could adversely affect the purpose of the Paediatric Use Regulation.

This issue was resolved in *C-125/10 Merck Sharp & Dohme v Deutsches Patent- und Markenamt (Merck)*, where the CJEU ruled that SPCs can be granted where less than five years have elapsed between the date of the application for the basic patent and the date of the first marketing authorisation, in order to enable patentees to seek paediatric extensions. The CJEU confirmed that the duration of the resulting SPC will be **negative** in those cases and should not be rounded up to zero. Thus, the total paediatric extension period will be less than six months in duration (rather than the entire six-month period).

Applications for paediatric extensions

Like SPCs themselves, applications for a paediatric extension must be lodged with the competent intellectual property office of the member state concerned.

Under **Article 7(3) and (4)**, applications for a paediatric extension *may* be made:

- (a) when the application for an SPC is lodged at the relevant national intellectual property office (provided the requirements of Article 8(1)(d) are satisfied); or
- (b) when the SPC application is pending (provided the requirements of Article 8(2) are satisfied).

However, applications for a paediatric extension *must* now be made not later than two years before the SPC expires.

Article 13 Medicinal SPC Regulation

3. The periods laid down in paragraphs 1 and 2 shall be extended by six months in the case where Article 36 of Regulation (EC) No 1901/2006 applies. In that case, the duration of the period laid down in paragraph 1 of this Article may be extended only once.

Article 36(1) and (4) of Regulation (EC) No 1901/2006 of 12 December 2006 on products for paediatric use

1. Where an application under Article 7 or 8 includes the results of all studies conducted in compliance with an agreed paediatric investigation plan, the holder of the patent or SPC shall be entitled to a six-month extension of the period referred to in Article 13(1) and (2) of the SPC Regulation.

The first sub-paragraph shall also apply where completion of the agreed paediatric investigation plan fails to lead to the authorisation of a paediatric indication, but the results of the studies conducted are reflected in the summary of product characteristics and, if appropriate, in the package leaflet of the medicinal product concerned.

4. Paragraphs 1, 2 and 3 shall apply to products that are protected by an SPC under the SPC Regulation, or under a patent which qualifies for the granting of the SPC.

Article 9 Medicinal SPC Regulation

1. The application for a certificate shall be lodged with the competent industrial property office of the Member State which granted the basic patent...

Article 7 Medicinal SPC Regulation

3. The application for an extension of the duration may be made when lodging the application for a certificate or when the application for the certificate is pending and the appropriate requirements of Article 8(1)(d) or Article 8(2), respectively, are fulfilled.

4. The application for an extension of the duration of a certificate already granted shall be lodged not later than two years before the expiry of the certificate.

5. Notwithstanding paragraph 4, for five years following the entry into force of Regulation (EC) No 1901/2006, the application for an extension of the duration of a certificate already granted shall be lodged not later than six months before the expiry of the certificate.

Plant SPC Regulation

The main principles and objectives of the Plant SPC Regulation are the same as those underlying the Medicinal SPC Regulation, namely to confer a level of protection for innovation which is equivalent to the Medicinal SPC Regulation by ensuring that patentees are adequately compensated for the period that elapses between the filing of a patent application for a new plant protection product and the grant of an authorisation to place that product on the market.

Much of the background information and case law explained above in the context of medicinal products therefore applies equally to the Plant SPC Regulation. However, certain key differences between the two regimes are described below.

Active substances

Article 1 Plant SPC Regulation includes a detailed definition of “plant protection products” and “products” which refers to preparations containing one or more active substances. Unlike the Medicinal SPC Regulation, the term “active substances” is defined to some extent under **Article 1(3)**.

The CJEU recently considered the meaning of active substances as applied to safeners in C-11/13 Bayer CropScience (**Bayer**). According to the referring court, safeners have at the most an “*indirect effect*” on plants or harmful organisms but are “*sometimes essential for the use of an active substance*”. Consistent with its earlier judgments in *MIT* (concerning excipients) and *GSK* (concerning adjuvants), the CJEU held that the term “active substance” may cover a substance intended to be used as a safener, where that substance has a “*toxic, phytotoxic or plant protection action of its own*”. If so (which is a matter for the referring court), it falls within the definition of a product under Article 1(8) and may result in the grant of an SPC, provided the necessary conditions in Article 3 are satisfied.

Articles 2 and 3 – Scope and conditions for obtaining a certificate

These provisions are very similar to those for the Medicinal SPC Regulation, except that both **Articles 2 and 3(1)(b)** refer not only to the corresponding regulatory Directive for plant protection products, but specifically to **Article 4** of Directive 91/414/EEC or an **equivalent provision of national law**.

In C-229/09 *Hogan Lovells International v Bayer CropScience* (**Hogan Lovells**), the CJEU was asked to consider whether a provisional marketing authorisation granted for a plant protection product under national

See e.g. recitals (4) to (7) Plant SPC Regulation

(4) Whereas the competitiveness of the plant protection sector, by the very nature of the industry, requires a level of protection for innovation which is equivalent to that granted to medicinal products by Council Regulation (EEC) No 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products (4);

(5) Whereas, at the moment, the period that elapses between the filing of an application for a patent for a new plant protection product and authorisation to place the said plant protection product on the market makes the period of effective protection under the patent insufficient to cover the investment put into the research and to generate the resources needed to maintain a high level of research;

(6) Whereas this situation leads to a lack of protection which penalizes plant protection research and the competitiveness of the sector,

(7) Whereas one of the main objectives of the supplementary protection certificate is to place European industry on the same competitive footing as its North American and Japanese counterparts;

Article 3(2) Plant SPC Regulation

2. The holder of more than one patent for the same product shall not be granted more than one certificate for that product. However, where two or more applications concerning the same product and emanating from two or more holders of different patents are pending, one certificate for this product may be issued to each of these holders.

Article 1(3) Plant SPC Regulation

For the purposes of this Regulation, the following definitions shall apply:

...

3. ‘active substances’: substances or micro-organisms including viruses, having general or specific action:

- (a) against harmful organisms; or
- (b) on plants, parts of plants or plant products;

legislation intended to transpose Article 8(1) Directive 91/414/EEC (rather than Article 4 Directive 91/414/EEC) was capable of satisfying Article 3(1)(b). The CJEU recognised that applications for provisional MAs submitted under Article 8(1) Directive 91/414/EEC must be examined in accordance with the scientific criteria applicable to definitive MAs under Article 4 Directive 91/414/EEC. The CJEU decided that this “link of functional equivalence” between the criteria meant that Article 3(1)(b) did not preclude the grant of an SPC based on a provisional MA. The CJEU also found support for its conclusion in the overall objectives of the Regulation and the specific wording of Article 13, which expressly refers to the assessment of duration of an SPC taking account of a provisional first MA in appropriate circumstances (see below).

However, the CJEU subsequently ruled in C-210/12 *Sumitomo Chemical v Deutsches Patent- und Markenamt (Sumitomo)* that Article 3(1)(b) is not satisfied by the grant of an “emergency” marketing authorisation under Article 8(4) Directive 91/414/EEC. In particular, it distinguished *Hogan Lovells* on the basis that emergency authorisations under Article 8(4) Directive 91/414/EEC lack the same “link of functional equivalence” with the scientific requirements as to reliability that are found in Article 4 Directive 91/414/EEC. Further, such emergency marketing authorisations are expressly described in Directive 91/414/EEC as not complying with Article 4.

Article 13 – Duration of the certificate

The general principles set out above concerning the assessment of duration of an SPC apply equally to plant protection products. However, an additional sub-paragraph is included in Article 13 Plant SPC Regulation which states:

"13(3). For the purposes of calculating the duration of the certificate, account shall be taken of a provisional first marketing authorisation only if it is directly followed by a definitive authorisation concerning the same product."

This sub-paragraph 13(3) was cited by the CJEU in *Hogan Lovells* when assessing the grant of SPCs based on provisional marketing authorisations (see above), although the significance of the words “only if it is **directly followed** by a definitive authorisation” is yet to be considered in detail by the CJEU.

Article 2 Plant SPC Regulation

Any product protected by a patent in the territory of a Member State and subject, prior to being placed on the market as a plant protection product, to an administrative authorisation procedure as laid down in Article 4 of Directive 91/414/EEC (6), or pursuant to an equivalent provision of national law if it is a plant protection product in respect of which the application for authorisation was lodged before Directive 91/414/EEC was implemented by the Member State concerned, may ... be the subject of a certificate.

Article 3(1)(b) Plant SPC Regulation

A valid authorisation to place the product on the market as a plant protection product has been granted in accordance with Article 4 of Directive 91/414/EEC or an equivalent provision of national law.

Articles 2 and 3(b) Plant SPC Regulation

are not referred to in the list of provisions said to apply equally when interpreting the Medicinal SPC Regulation (see Recital (17) Plant SPC Regulation).

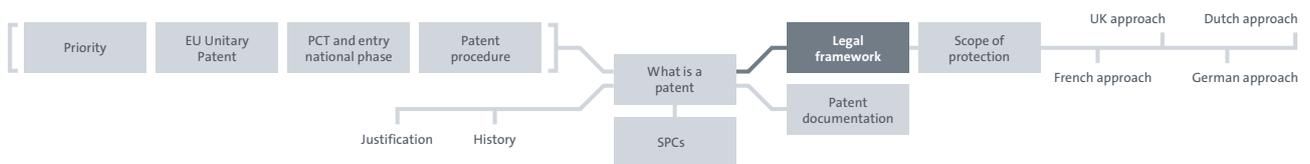
Article 4 Directive 91/414/EEC sets out the requirements for a definitive marketing authorisation.

Article 8(1) Directive 91/414/EEC sets out the requirements for a provisional marketing authorisation, as considered by the CJEU in *Hogan Lovells*.

Article 8(4) Directive 91/414/EEC sets out the requirements for an emergency marketing authorisation, as considered by the CJEU in *Sumitomo*.

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.

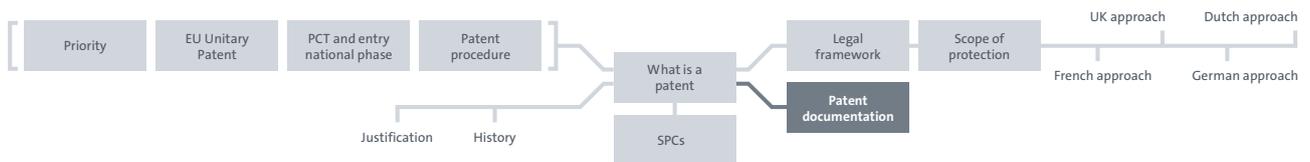
Both the national courts and the UPC are bound by the **Enforcement Directive (2004/48/EC)**, which is concerned with civil law measures, procedures and remedies relating to the enforcement of patent rights.

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.

Patent documentation

Essentials: Documentation



Applying for a patent

The formal requirements for a European patent application are to be found in **Article 78** of the European Patent Convention (EPC).

The European Patent Office accepts applications under the EPC and the Patent Cooperation Treaty (PCT) only. Applicants wishing to obtain patent protection in a small number of states only may be better advised to seek protection directly with the national offices concerned. The national requirements for the contracting states to the EPC are identical to those under Article 78 EPC.

Article 78 EPC

Requirements of a European patent application

- (1) A European patent application shall contain:
- (a) a request for the grant of a European patent;
 - (b) a description of the invention;
 - (c) one or more claims;
 - (d) any drawings referred to in the description or the claims;
 - (e) an abstract,

and satisfy the requirements laid down in the Implementing Regulations.

- (2) A European patent application shall be subject to the payment of the filing fee and the search fee. If the filing fee or the search fee is not paid in due time, the application shall be deemed to be withdrawn.

Languages

Applications may be filed at the EPO in any language. However, according to Article 14(2) EPC, applications made in a language other than the EPO's three official languages (English, French and German) must be translated into one of the official languages in accordance with the Implementing Regulations. **Rule 6(1) EPC** requires the translation to be filed within two months of the date of filing.

The official language of the EPO in which the European patent application is filed or into which it is translated is used as the language of the proceedings in all proceedings before the EPO (Article 14(3) EPC). The specification of the European patent is published in the language of the proceedings, but is also required to include a translation of the claims into the other two official languages of the EPO (Article 14(6) EPC).

Rule 6 EPC

Filing of translations and reduction of fees

(1) A translation under Article 14, paragraph 2, shall be filed within two months of filing the European patent application.

The role of documentation in the application process

The elements of the documentation – the description, drawings and claims (collectively referred to as the specification) and the abstract – all have different functions within the application.

The specification (as a whole) details the patentee's invention. Elements of it are used to determine the patent's scope of protection. It is therefore the body of the patent itself. The specification is examined in order to ensure that the subject-matter fulfils the requirements of patentability. The specification also has a role to play in determining the scope of protection, as it includes the claims, which are interpreted in the light of the description and drawings. The abstract is largely an administrative document designed to assist in the searching of patents and applications.

The abstract

The abstract provides brief technical information about the disclosure as contained in the specification. Whilst it is initially supplied by the applicant, the EPO is responsible for finalising its content (**Rule 66 EPC**).

The role of the abstract is solely to provide technical information in order to assist searching within the technical field in question, in other words to provide sufficient information to enable the searcher to assess whether there is any need to consult the patent application itself. The abstract has no role to play in the interpretation of the claims (and hence in determining the patent's scope of protection) (**Article 85 EPC**).

Rule 66 EPC

Definitive content of the abstract

Upon drawing up the European search report, the European Patent Office shall determine the definitive content of the abstract and transmit it to the applicant together with the search report.

Article 85 EPC

Abstract

The abstract shall serve the purpose of technical information only; it may not be taken into account for any other purpose, in particular for interpreting the scope of the protection sought or applying Article 54, paragraph 3.

Requirements for the abstract

Rule 47 EPC sets out the requirements for the content of the abstract.

The abstract must:

- Indicate the title of the invention.
- Include a concise summary of the disclosure.
- Indicate the technical field of the invention.
- Be accompanied by an indication of the figure of the drawings that should accompany it.

The abstract should not:

- Contain statements on the alleged merits or value of the invention.

It must preferably be no more than 150 words in length.

The specification

The specification is the body of the patent. It is the umbrella term used to describe a package that includes the description, drawings and claims.

The specification can be seen as a *quid pro quo* of patent protection, i.e. as the enabling information that will pass into the public domain at the end of the patent term. As such, there must be synergy between the claims (which define the invention and its scope of protection) and the description, so that the description enables a **notional person skilled in the art** to do at least what it is that the claims protect. This requirement is often referred to as “sufficiency of disclosure”.

Person skilled in the art

This is a judicial construct intended to assist in the achievement of objectivity within various aspects of patent law. This notional skilled person (the skilled addressee) is the person to whom the patent and its claims are directed.

The skilled addressee may comprise a team of individuals of different skills. They work in the area of the patent; are interested in its function; are not inventive; but have a comprehensive background general knowledge (the common general knowledge).

The description and drawings

The application must disclose the invention in a manner that is sufficiently clear and complete for it to be carried out by a person skilled in the art. This requirement is satisfied by the description and the drawings.

These two elements are therefore the enabling part of the specification – i.e. the part that teaches the skilled person to put the patent into practice and the part that passes the advance made by the patentee into the public domain once the patent term has come to an end and protection has expired.

The content of the description

The description must do the following things:

- (a) Identify the technical field to which the invention relates.
- (b) Indicate the background art which, as far as is known to the applicant, can be regarded as useful to understand the invention, draw up the search report and examine the patent application.
- (c) Disclose the invention in such a way that the technical problem or problems with which it deals can be appreciated and the solution can be understood. It should also state any advantageous effects of the invention with reference to the background art;
- (d) Briefly describe the figures in the drawings (if any).
- (e) Describe in detail at least one way of carrying out the invention claimed, using examples where appropriate.
- (f) Indicate explicitly (where this is not obvious) the manner in which the invention is industrially applicable.

Rule 42 EPC
Content of the description

Drawings

The requirements as to the form and content of the drawings are set out in Rule 46 EPC. Most of these are merely formal: minimum margins, for example, are prescribed; drawings must be in black and white; their scale must allow details to be distinguished without difficulty when reduced in size to two-thirds.

Only absolutely indispensable text matter may be included in the drawings.

Claims – requirements

The claims are the heart of the patent. They define the invention, demarcating what is old from what is new. They also form the boundary of the exclusive territory within which the patentee is entitled to operate, i.e. they define both what must be patentable and also what is protected by the patent.

The application must contain “one or more claims” (Article 78(1) EPC).

Since the extent of the protection conferred by a European patent or patent application is determined by the claims (interpreted with the help of the description and the drawings), the clarity of the claims is of the utmost importance (**Article 69(1) EPC**).

The requirements for the claims can be found in **Article 84 EPC**.

Article 69 EPC
Extent of protection
(1) The extent of the protection conferred by a European patent or a European patent application shall be determined by the claims. Nevertheless, the description and drawings shall be used to interpret the claims.

Article 84 EPC
Claims
The claims shall define the matter for which protection is sought. They shall be clear and concise and be supported by the description.

Claim types and categories

There are two basic categories of claims:

- Claims to a physical entity (product or apparatus claims)
- Claims to an activity (process or use claims)

The category of claim dictates the acts of infringement that will be relevant to it; acts of infringement differ depending on whether the claim is for a **product** or a **process** (i.e. a physical entity or an activity).

Product-by-process claims

Claims for products defined in terms of a process of manufacture are allowable only if the products as such fulfil the requirements for patentability, e.g. *inter alia* that they are new and inventive. A product is not rendered novel merely by the fact that it is produced by means of a new process (see decision T 150/82 of the Boards of Appeal of the EPO). A claim defining a product in terms of a process is to be construed as a claim to the product as such.

Claims may be independent (i.e. they may stand by themselves) or dependent (i.e. they are parasitic upon another claim).

The claims must define the matter for which protection is sought

The claims must be drafted in terms of the “technical features of the invention” (**Rule 43(1) EPC**). They should not therefore contain any statements relating to commercial advantages or other non-technical matters. Statements of purpose will be allowable if they assist in defining the invention.

Wherever appropriate (i.e. this is not an absolute requirement), claims should be constructed in two-part form:

- The first part contains a statement indicating “the designation of the subject-matter of the invention”, i.e. the general technical class of apparatus, process, etc. to which the invention relates, followed by a statement of “those technical features which are necessary for the definition of the claimed subject-matter but which, in combination, are part of the prior art”.
- The second part is often known as the “characterising portion”, and states the features that the invention adds to the prior art, i.e. the technical features for which (in combination with the features stated in the first part) protection is sought.

Acts of infringement

For a product: making, offering, putting on the market, or using a product which is the subject-matter of the patent, or importing or stocking the product for these purposes (Article 25(a) CPC).

For a process:

– using a process which is the subject-matter of the patent or, when the third party knows, or it is obvious in the circumstances, that the use of the process is prohibited without the consent of the proprietor of the patent, offering the process for use in the territories of the contracting states (Article 25(b) CPC);

– offering, putting on the market or using a product obtained directly by a process which is the subject-matter of the patent, or importing or stocking the product for these purposes (Art. 25(c) CPC).

Rule 43 EPC

Form and content of claims

(1) The claims shall define the matter for which protection is sought in terms of the technical features of the invention. Wherever appropriate, claims shall contain:

(a) a statement indicating the designation of the subject-matter of the invention and those technical features which are necessary for the definition of the claimed subject-matter but which, in combination, form part of the prior art;

(b) a characterising portion, beginning with the expression “characterised in that” or “characterised by” and specifying the technical features for which, in combination with the features stated under sub-paragraph (a), protection is sought.

The claims must be clear and concise

The claims define the invention and dictate the patent's scope of protection. It is therefore essential that they are clear.

The requirement of clarity relates both to individual claims and to the claims as a whole. The claims must not only be comprehensible from a technical point of view, but must also clearly define all the essential features of the invention (see decision T 32/82 of the Boards of Appeal of the EPO).

In the light of the different acts of infringement and other considerations that may apply, the wording of a claim should leave no doubt as to its category or type. Inconsistencies between the description and the claims should also be avoided.

The claims must be supported by the description

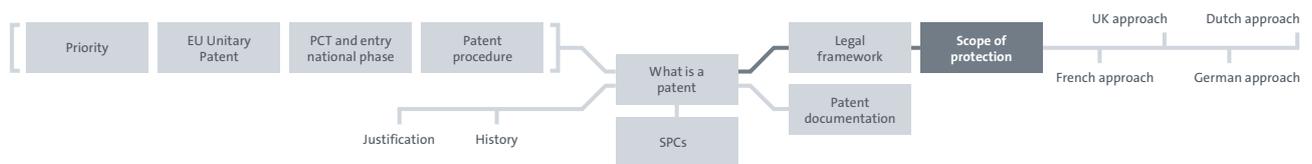
In order for the award of the patent monopoly to be justified, the patentee's benefit from the zone of exclusivity that the patent provides must be balanced against the public's benefit from the patent disclosure. This requirement is reflected in the requirement of Article 84 EPC for the claim to be "supported by the description".

In the straightforward case, this means that the patent may not claim more than it discloses or teaches. However, the requirement for support also applies to features which are explicitly presented in the description as being essential for carrying out the invention (see decision T 1055/92 of the Boards of Appeal of the EPO). A lack of essential features in the independent claim(s) is therefore to be dealt with under the clarity and support requirements.

The requirement for support is closely linked to the requirement of sufficiency of disclosure. The specification must teach the person skilled in the art to perform the invention to the extent of the claims. Lack of support may therefore be challenged as insufficiency post-grant.

Scope of protection

Essentials: SoP



Introduction

A patent is an *intangible* property right. The abstract nature of this right makes the application of a traditional legal analysis of property somewhat difficult. In cases concerning *tangible* property there is rarely, if ever, the need to enter into complex debate about the boundaries of the property concerned. It may be that the rights affected need some clarification, but in general boundaries are clear or can be relatively easily determined.

This is not the case with patents. A patent may be said to provide legitimate protection to an “inventive idea” or the “subject-matter” that lies behind an invention. This is quite often wider than the projection or expression of the idea in real space, and, given its abstract nature, the only sensible way in which this “matter” can be contained is to pin it down in words. The required method of doing this is to draft a series of *claims* following a descriptive specification of the invention and, where necessary, to include drawings. It is the job of the claim drafter to effectively enclose the invention without straying into the prior art and without overly stretching the claim to encompass things that the inventor has not actually invented, or not described.

Claims define the invention

Claims are carefully worded sentences that serve to define the invention. They provide the means for the public, i.e. the interested reader of a patent (and the courts), to understand and visualise what the patentee has marked out as his invention, and therefore what invention is claimed as his exclusive property. Claims are not evidence of a contractual agreement; they are a unilateral statement of definition in the words of the inventor.

Claims are, accordingly, critical when it comes to:

- (a) determining the scope of the protection granted, and
- (b) establishing the validity of a patent.

There are two approaches concerning the role that a patent's claims will play when determining the scope of a patent. The names given to these positions are "peripheral definition theory" and "central definition theory".

Peripheral definition: Under the peripheral definition approach, claims define the outer boundaries or limits of protection. They form the linguistic equivalent of "fence posts" and enclose the patentee's exclusive territory, marking its outer limits. The major advantage of this approach is that the scope of protection will be relatively clear to any third party reading the patent, thereby providing certainty to the grant.

Central definition: Under the central definition approach, the scope of protection is determined by finding the principle underlying the invention (the "inventive idea") by looking at the teaching in the specification as a whole. The claims are treated merely as sign posts; for while they may be the starting point for the assessment, the courts are not strictly bound by their actual wording. Under this theory, patent scope is established based upon the inventor's contribution to the art. The central definition approach has the advantage of providing a flexible degree of protection for the patentee. However, it may also be seen to suffer in terms of certainty when compared with the alternative interpretative theory.

Summary of requirements under the EPC

Under the EPC, the claims define the invention (**Article 84 EPC**). They are also used to determine the patent's scope of protection (**Article 69 EPC**).

Claims are written in peripheral style – separating what is old and obvious (which by definition must be outside of the patentee's exclusive territory) from that which is new and inventive.

The claims must be interpreted in light of the description and also the drawings (**Article 69 EPC**). It is not permissible to merely look at the dictionary definition of a word; the word must be interpreted in the context in which it is used. However, the claims should not be used merely as guidelines – they must play a determinative part in deciding on the patent's scope.

Equivalents

In deciding whether something falls within the scope of a claim, due account should also be taken of any element which is equivalent to an element specified in the claims. However, exactly how this is to be interpreted, and the significance or weight that is to be attached to such equivalents, is far from certain, as we shall see. In all cases, the reader of the patent is deemed to be “the skilled reader” (see below).

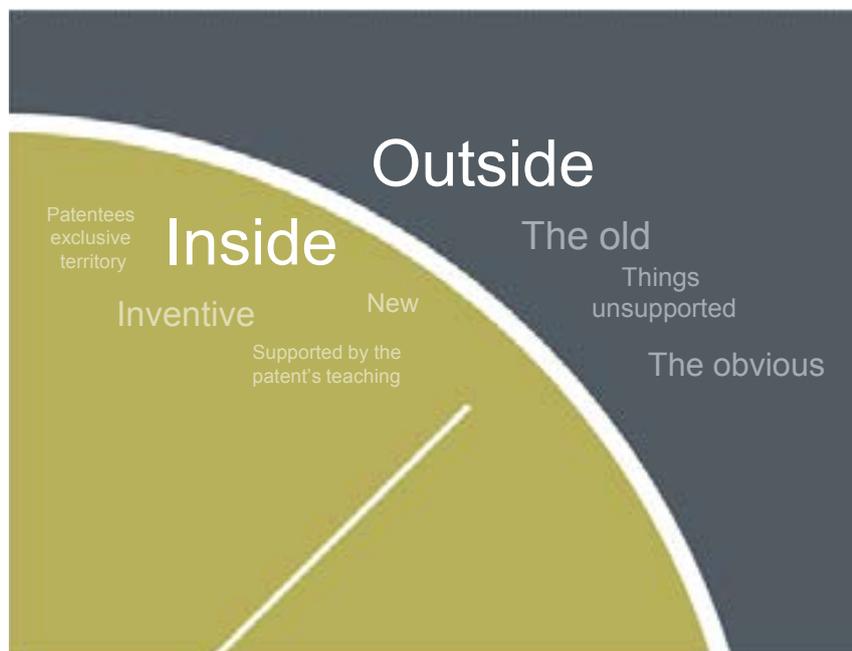
Article 84 EPC Claims

The claims shall define the matter for which protection is sought. They shall be clear and concise and be supported by the description.

Article 69 EPC Extent of protection

(1) The extent of the protection conferred by a European patent or a European patent application shall be determined by the claims. Nevertheless, the description and drawings shall be used to interpret the claims.

(2) For the period up to grant of the European patent, the extent of the protection conferred by the European patent application shall be determined by the claims contained in the application as published. However, the European patent as granted or as amended in opposition, limitation or revocation proceedings shall determine retroactively the protection conferred by the application, in so far as such protection is not thereby extended.



Putting claim construction into practice: some fundamentals

The construction of patent claims normally involves determining the contextual meaning of ordinary words of a language, for whatever reason. This is a question of law **not** fact. It is accordingly **not** a question for an expert, but one for a judge. There is an exception to this, however. Expert evidence may legitimately be given on the meaning of technical words in the context of the specification.

The claims are constructed by looking through the eyes of the notional addressee, i.e. the **person skilled in the art** (see below). In the context of claim construction, it is therefore not permissible for a judge (or indeed anyone else) to ask “what does this claim mean to me?” The correct question is to ask what the skilled addressee would consider the words in the claim to mean. Claims are therefore read against the addressee’s background knowledge, in other words **the common general knowledge of the art**.

Moreover, the scope of the claim should be interpreted without reference to the alleged infringement or to any prior art.

The EPC does not govern issues of infringement, which is determined in accordance with national law. Accordingly, under the EPC there is no set date at which the claims must be interpreted for the purpose of infringement proceedings. There is, as yet, no consistent approach that has been adopted across the member states. Indeed, different courts within some states have construed the scope of the claims as of different times in different cases. Obviously, the date at which the claims are construed could have significant repercussions on their scope, and this unharmonised approach is therefore open to criticism. The following dates have been used:

The priority date: *Schneidmesser I* (German Supreme Court) (2002) 33 IIC 873.

The filing date: *Biogen v Medeva* (UK House of Lords) [1997] RPC 1.

The publication date: *Catnic Components v Hill & Smith* (UK House of Lords) [1982] RPC 183 – in fact, this is the generally accepted date of interpretation in the UK.

The date of infringement is also sometimes used in certain states.

The person skilled in the art or the “skilled addressee”

The person skilled in the art is referred to in a number of places within the EPC. For example, **Article 56** declares 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. **Article 83**, concerning sufficiency of disclosure, and Article 69 (extent of protection) also refer to this notional individual. However, the importance of this “skilled addressee” is far broader.

The notional person skilled in the art is a legal fiction intended to assist in the objective interpretation of the claims, as well as to provide objectivity when considering other matters of patent law. For example, when considering whether an invention is new, the prior art must be viewed through the eyes of the skilled addressee. Equally, the viewpoint of the skilled person must be used to assess whether an amendment to the claims or specification is impermissible as “adding matter”.

In fact, the role of this judicial construct is central to patent law.

Article 56 EPC Inventive step

An invention shall 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. If the state of the art also includes documents within the meaning of Article 54, paragraph 3, these documents shall not be considered in deciding whether there has been an inventive step.

Article 83 EPC Disclosure of the invention

The European patent application shall disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.

The person skilled in the art: some fundamental criteria

The level of skill that the person skilled in the art is deemed to possess will, obviously, be linked to the specific patent in question, i.e. it will be dependent upon the art. The skilled addressee of a mechanical invention will not be the same as that for one in the field of biotechnology. However, the level of skill possessed by the addressee will be the same for all purposes related to the particular patent.

Given that we are considering the mind of a notional person skilled in the art, we must inevitably attempt to determine the broader context too. What information would he accept without question? What would he reject out of hand? What are his prejudices? This inevitably entails considering the common general knowledge of the art.

In approaching construction, it is therefore essential to answer a number of questions:

- Who is the person skilled in the art in respect of this particular invention?
- What is his common general knowledge?

The art can be ascertained by examination of the patent. As general considerations, the skilled person:

- Can comprise a team of individuals with different qualifications depending on the technology in question.
- Is not generally of exceptional skill or knowledge – i.e. is not generally at the top of his profession. But, depending again on the technology involved, a postgraduate degree might be needed.
- Has carefully read all of the literature – and has an unlimited capacity for absorbing the relevant literature.
- Possesses the common general knowledge in the field/art in question.
- Can carry out simple trial-and-error experiments, but cannot be required to engage in a research programme.
- Is definitely not inventive.

The common general knowledge: some fundamental criteria

The “common general knowledge” of an art is a shorthand way of referring to the knowledge which is widely known and generally regarded as a good basis for further action by the bulk of those engaged in the art to which the invention relates. It has been described as the skilled worker’s toolbox. It must be distinguished from what is known as the “state of the art”.

It will include those things that the skilled person knows exists and which he would refer to as a matter of course if he could not actually remember them and which he generally understands are sufficiently reliable to use as a foundation for further work. However, it is not everything that would turn up in a literature search.

It also includes any commonly held prejudice of the trade (e.g. that something would definitely not work, or that a particular way of doing things is absolutely the best way of doing something). In *Dyson v Hoover*, [2001] EWCA Civ 1440, the court considered that the vacuum cleaner industry’s fixation on cleaners with disposable dust bags set the notional skilled addressee’s mental horizon, making a true inventor of the individual who was able to lift his eyes above the horizon and envisage a bag-free machine. Common general knowledge may occasionally include the contents of very well-known patent specifications.

Proving the common general knowledge

Common general knowledge is proved at trial as a question of fact. Accordingly, expert evidence is available to determine what the common general knowledge was at a relevant time. However, care must be taken in this respect: just because something was known to a particular witness does not automatically mean it is part of the common general knowledge. Equally, just because something is recorded in a particular document does not automatically make it common general knowledge, even if the document is widely read. A piece of knowledge only becomes general knowledge when it is generally known and accepted without question by the bulk of those who are engaged in the particular art, in other words, when it becomes part of their common stock of knowledge relating to the art.

T 890/02 BAYER/Chimeric Gene explains that the common general knowledge is normally to be found within encyclopaedias, handbooks and dictionaries on the subject in question, but that such knowledge is clearly distinct from the state of the art as a whole. Knowledge only becomes common general knowledge when it is included in general or specialised handbooks or in encyclopaedias after being accepted, integrated and shared by the scientific community.

T 890/02 (Chimeric gene/Bayer)

Summary

The person skilled in the art is a legal fiction designed to provide a degree of objectivity when it comes to assessing issues in various areas of patent law, including claim construction/determination of scope, assessment of inventive step and sufficiency.

The skilled addressee is not a real person, and may be a composite team of people with various skills. They are interested in the field(s) of the invention and can make simple trial-and-error experiments to overcome difficulties in the disclosure/prior art where it would be obvious to do so. However, they are assumed to possess no inventive capacity.

The skilled person possesses the common general knowledge of the art – things known and accepted without question by the majority of those in it. The common general knowledge may determine how the addressee approaches the solution to a technical problem, the invention or the prior art, and may determine whether a particular avenue of progress is likely or not.

A doctrine of equivalents? A vexed question

An equivalent may be defined as a variant understood to be functionally identical to an integer in a claim yet falling outside of its literal meaning. Examples could include claims referring to a compound containing a group II metal and an infringer using manganese (a non-group II metal, but one having equivalent properties in certain contexts) instead, or claims referring to loose ends secured with a clamp, and an infringer choosing to secure them by means of a weld.

Whether the substitution of a claimed integer for equivalent means properly falls within the scope of the patent is a vexed question. Some states (Germany and France, for example) see the protection of equivalents as integral to the concept of providing the patentee with fair protection. Others, such as the UK, deny that there is any room within Article 69 EPC for equivalents to extend protection outside of the claim; the claim uses words of the patentee's own choosing.

Equivalents under the EPC

The lack of harmonisation on the matter of equivalents prompted the EPC Drafting Committee to propose a new Article 2 for the Protocol on the Interpretation of **Article 69 EPC** when the Convention was amended in November 2000. The delegates at the Munich Conference therefore accepted the inclusion of the following words into the Protocol:

"For the purpose of determining the extent of protection conferred by a European patent, due account shall be taken of any element which is equivalent to an element specified in the claims."

One may be forgiven for thinking that such a statement would be read as mandating the adoption of an EPC doctrine of equivalents. However, this is not the way in which the UK courts have interpreted it. Lord Hoffmann in *Kirin-Amgen* (UK House of Lords) [2005] RPC 9 held that there could be no doctrine of equivalents under the EPC. All that Article 2 of the new Protocol could require was that equivalents could *"be an important part of the background of facts known to the skilled man which would affect what he understood the claims to mean"*.

Article 69 EPC

Extent of protection

(1) The extent of the protection conferred by a European patent or a European patent application shall be determined by the claims. Nevertheless, the description and drawings shall be used to interpret the claims.

(2) For the period up to grant of the European patent, the extent of the protection conferred by the European patent application shall be determined by the claims contained in the application as published. However, the European patent as granted or as amended in opposition, limitation or revocation proceedings shall determine retroactively the protection conferred by the application, in so far as such protection is not thereby extended.

File wrapper estoppel

File wrapper estoppel is a US term used to describe the attempted use of the prosecution history as recorded in the file at a patent office to constrain the interpretation that may be placed on a patent's claims following grant. In essence, it means that a patentee is estopped from, say, arguing for a broad interpretation of a claim so as to reclaim subject-matter surrendered during prosecution in an attempt to secure the grant. In other words, the patentee is tied to any promises or concessions made and recorded during prosecution of the patent.

There is still no harmonised approach mandated by the EPC. Indeed, the text of the EPC does not mention the term “file wrapper estoppel”. Some states insist that such a doctrine be utilised and others disavow its relevance under the EPC. No clear picture emerges.

Arguments for and against file wrapper estoppel

Arguments in favour of this doctrine include:

- The prosecution file relates to the claims at issue and is therefore clearly relevant.
- In practice, the file is always consulted by the patent attorney when prosecuting.

Arguments against include:

- Article 69 EPC and the Protocol are silent on the doctrine.
- Despite being put forward at the Munich Conference, a provision designed to include file wrapper estoppel was rejected.
- Life is too short to trace the file and consult it as a matter of course.
- Legal certainty would favour not looking at the file.
- The expense of requiring an interested member of the public to consult the prosecution file whenever a question of scope of protection arises would be totally disproportionate to its utility. Often the file would require translation in such circumstances.

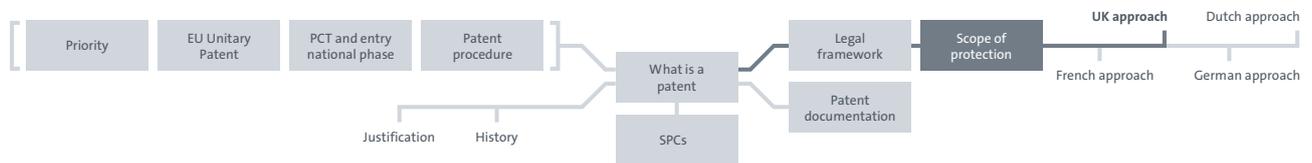
File wrapper estoppel: national practice

As noted, there is no harmonised position. States are free to make up their own minds as to the relevance (or otherwise) of the file wrapper. Accordingly, varying practice can be seen across the EPC contracting states.

- The Dutch position is that the file is relevant and may always be read.
- The German position is the opposite – Article 69 EPC and the Protocol do not mention it and therefore it is not relevant to construction. However, the 2011 Federal Supreme Court judgments *Occlusion Device* (2011) 42 IIC 851 and *Polymer Foam* (X ZR 117/11) have added that it is an open question whether patent publications such as the officially published patent application or earlier versions of the patent (which have been modified for instance in opposition proceedings) might be relevant to claim construction: differences between the content of earlier publications and the final patent might help in construing the claims of the final patent.
- The English and French sit somewhere in-between. The English courts generally do not look at the file (and indeed, when asked, usually state that it is not appropriate to do so) but nevertheless will concede to examining it where it is really necessary to do so in order to construe the claim – per *Walker LJ* in [2001] EWCA Civ 1589.

The French position is that no such doctrine exists, but that consideration of the file may be persuasive in some cases.

The UK approach (Supplementary reading)



Claims and the scope of protection under the EPC – history

Before the adoption of the EPC, some European states (e.g. the UK and Switzerland) applied “peripheral claiming”, while others (e.g. Germany and the Netherlands) applied “central claiming”. In the UK, therefore, claims served both to define the invention and to demarcate or limit its extent (“what is not claimed is disclaimed”). In Germany, on the other hand, they only defined the invention. The scope of protection was determined by generalisation of the inventive concept, and this was largely unaffected by the exact words used in the claims. Claims were treated as a starting point or point of departure (“*Ausgangspunkt*”).

Traditions of claim construction were also different between the “peripheral” states and the “central” states. In the former, claims were treated more strictly. Their wording was critical to the extent of patent protection (on the basis that the patentee had chosen the words in question and should therefore be limited to them). In the latter, the actual words of the claims were less important – protection could even be given to things falling far from the claims, as long as they would have been obvious to the skilled person reading the patent. This potentially extended protection was given on the basis that the inventor should be able to reap his reward to the extent that the invention genuinely contributed to the art.

1977: Changes wrought by the EPC – Article 69 EPC

With the passage of the EPC, a harmonised approach to the treatment of patent claims was adopted by the contracting states. This was brought about by Article 69 EPC, which (in its original wording) stated:

"The extent of the protection conferred by a European patent or a European patent application shall be determined by the terms of the claims. Nevertheless, the description and drawings shall be used to interpret the claims."

Article 84 EPC Claims

The claims shall define the matter for which protection is sought. They shall be clear and concise and be supported by the description.

"Peripheral" claiming had won the day. Unfortunately, however, the exact wording of Article 69 EPC varied slightly in translation between each of the official texts of the EPC – i.e. the English, German and French ("*terms of the claims*" v "*Inhalt der Patentansprüche*" v "*teneur des revendications*" respectively). As one commentator noted at the time, "it is very unfortunate that this divergence between the ... texts should coincide with their respective national traditions." The wording could lead a British judge to read the English version as confirmation of his traditional approach, and the same could hold true, to a lesser extent, for his German counterpart.

Protocol on the Interpretation of Article 69 EPC

There was a similar fear within the Drafting Committee that the past practices of member states might lead them to interpret Article 69 EPC in a manner that was inconsistent with its intent (and more in line with their own previous practice). It was therefore decided to add an interpretative protocol.

In its original form (shown on the right), this simply required avoidance of two extreme positions: overly literal and overly liberal – caricatures of the pre-EPC UK and German approaches respectively.

The wording of the Protocol was described at the time as "**a masterpiece of ambiguity**". It certainly provided broad latitude for states to apply different standards to the interpretation of claims, as long as they did not stray into the forbidden territory of either ignoring the description and drawings or treating the claims merely as guidelines.

At the diplomatic conference held in Munich in November 2000 (the Munich Conference), concern was expressed that Article 69 EPC and its Protocol were somewhat unclear, having regrettably not achieved, "to the extent desired, the goal of ensuring as uniform an application and interpretation as possible." An amended text was suggested, which came into force in December 2007.

Protocol on the Interpretation of Article 69 EPC (original text)

"Article 69 should not be interpreted in the sense that the extent of the protection conferred by a European patent is to be understood as that defined by the strict, literal meaning of the wording used in the claims, the description and drawings being employed only for the purpose of resolving an ambiguity found in the claims. Neither should it be interpreted in the sense 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 patentee has contemplated. On the contrary, it is to be interpreted as defining a position between these extremes which combines a fair protection for the patentee with a reasonable degree of certainty for third parties."

"Masterpiece of ambiguity" is from Baillie, "Where Goes Europe? The European Patent" (1976) 58 J.P.O.S. 153, 167

Article 69 and its Protocol (as amended)

Of particular concern to the drafters of the “Basic Proposal” put before delegates at the Munich Conference were inconsistencies in the treatment of so-called “equivalents”, which they believed had led to significant practical divergence between member states.

Article 69 underwent relatively mild amendment to remove the words “*terms*”/“*Inhalt*”/“*teneur*” and the two words that followed directly, so that the extent of protection is now determined simply by “the claims”, interpreted in the light of the description and drawings.

The Protocol on the Interpretation of Article 69 underwent more serious amendment (see right). Its new Article 2 was intended to assist in curing the perceived discrepancies between states on the matter of “equivalents”.

A bundle of national patents – the continuing problem

Patents applied for under the EPC become national patents upon grant. Infringement is therefore a question for the national courts. Given that there is currently no common appeal court in Europe, and the Boards of Appeal of the EPO have jurisdiction over the elements of patentability and process under the EPC only, the courts of the member states are effectively supreme when it comes to questions of infringement.

This can cause problems. One example is the infamous *Improver v Remington* litigation, wherein the same patent was litigated in respect of the same infringement in various European states (including Germany, the Netherlands and the UK) with different outcomes: in the UK there was held to be no infringement, whereas both the German and Dutch courts thought there was.

Despite increased judicial co-operation in recent years, there is still variation in claim construction between jurisdictions within the EPC contracting states.

Article 1

"Article 69 should not be interpreted ~~in the sense~~ as meaning that the extent of the protection conferred by a European patent is to be understood as that defined by the strict, literal meaning of the wording used in the claims, the description and drawings being employed only for the purpose of resolving an ambiguity found in the claims. ~~Neither~~ Nor should it be ~~interpreted in the sense~~ 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 ~~patentee~~ 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 ~~patentee~~ patent proprietor with a reasonable degree of legal certainty for third parties."

Article 2

"For the purpose of determining the extent of protection conferred by a European patent, due account shall be taken of any element which is equivalent to an element specified in the claims."

Germany: (1993) 24 IIC 838

Netherlands: (1993) 24 IIC 832

UK: [1990] FSR 181

The skilled person – an example

Vericore v Vetrepharm, [2003] EWHC 11, concerns a patent for controlling sea lice infestation in salmon and other sea fish, a particular problem in fish farms. The patent suggested using pyrethroid pesticides (well known for treating pests in sheep and cattle) to treat the fish. One of the key arguments in the case was whether this new use of pyrethroids would have been obvious. The patentee argued that it would not. The skilled person, it claimed, would be a fish health expert and would consider the compound too toxic to administer, not realising that there might be a dosage window in which the compound would kill the lice but not harm the fish. The court did not agree:

"The relevant addressee would have both fish health expertise and toxicology expertise. In real life it would be a team. This can be looked at in two ways. D1 suggests that synthetic pyrethroids are probably the way forward. If this were read by a toxicologist, say someone in the employ of a company making such compounds, he would call in a fish health specialist to consider the application of this class of compounds to fish. On the other hand, if the prior art were read by a fish health expert who was ignorant of pyrethroid toxicology, he would inevitably call in someone with that expertise. In either event one ends up with an addressee having both areas of expertise."

The skilled person – a summary

One of the best judicial discussions of the person skilled in the art can be found in *Lilly Icos v Pfizer* in the English High Court ([2001] FSR 16). The case concerns the patent on the most famous little blue pill in the world, and although the decision was overturned on appeal, the discussion of the skilled addressee is hard to beat:

"This is not a real person. He is a legal creation. He is supposed to offer an objective test of whether a particular development can be protected by a patent. He is deemed to have looked at and read publicly available documents and to know of public uses in the prior art. He understands all languages and dialects. He never misses the obvious nor stumbles on the inventive. He has no private idiosyncratic preferences or dislikes. He never thinks laterally. He differs from all real people in one or more of these characteristics."

The UK approach to the construction of claims – purposive construction

Article 69 EPC is incorporated into UK law as **Section 125(1) of the Patents Act 1977**. Somewhat pointlessly, rather than simply copying the official English version of Article 69 into the UK statute, the Parliamentary draftsman chose to reword the provision. It is, however, not suggested that the two are anything but identical in scope. The Protocol on the Interpretation of Article 69 is incorporated into UK law by virtue of **Section 125(3) PA 1977**: "The Protocol on the Interpretation of Article 69 of the European Patent Convention (which Article contains a provision corresponding to subsection (1) above) shall, as for the time being in force, apply for the purposes of subsection (1) above as it applies for the purposes of that Article."

Section 125(1) Patents Act 1977

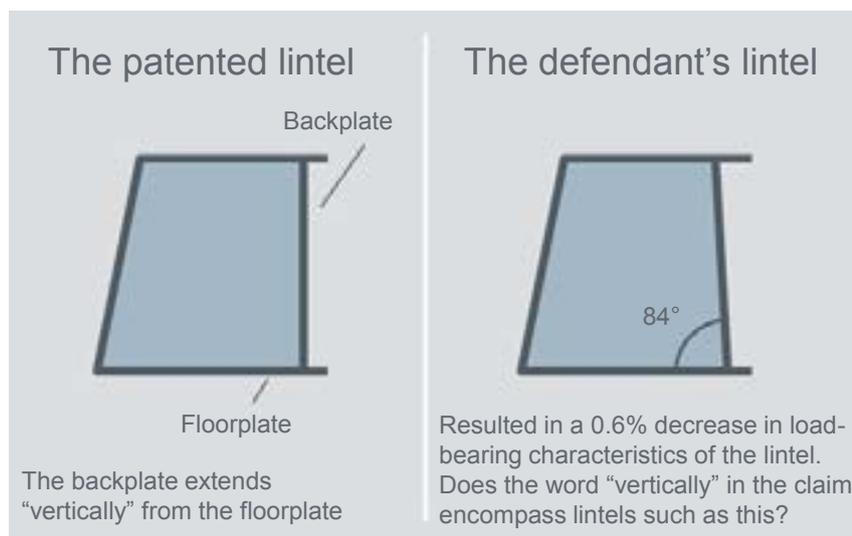
For the purposes of this Act an invention for a patent for which an application has been made or for which a patent has been granted shall, unless the context otherwise requires, be taken to be that specified in a claim of the specification of the application or patent, as the case may be, as interpreted by the description and any drawing contained in that specification, and the extent of the protection conferred by a patent or application for a patent shall be determined accordingly.

→ The *Catnic* approach

The first case to come before the higher courts in the UK following the EPC's entry into force was *Catnic Components v Hill & Smith* [1982] RPC 183. It actually concerned a patent granted under the old (pre-EPC) legislation, but was subsequently held to have established an approach that is compatible with Article 69 EPC and the Protocol.

The case concerned the interpretation of the phrase “extending vertically” in the patent for a new type of steel lintel for placing over the top of doors and windows to support the wall above.

The patentee claimed a backplate “extending vertically” from a floorplate. The defendant produced a lintel in which the backplate was inclined at 84 degrees from the floorplate. Was this within the claim?



→ The *Catnic* question

Lord Diplock, giving the lead judgment in the House of Lords (the UK’s highest court), held that the question could not be answered by looking at the literal meaning of the word “vertical” as understood by a geometer. A different approach was required:

“The question in each case is: whether persons with practical knowledge and experience of the kind of work in which the invention was intended to be used, would understand that strict compliance with a particular descriptive word or phrase appearing in a claim was intended by the patentee to be an essential requirement of the invention so that any variant would fall outside the monopoly claimed, even though it could have no material effect upon the way the invention worked.”

Accordingly, in the case in hand, the court thought that the patentee could not have intended to restrict himself to what was exactly geometrically vertical. 84 degrees was still vertical for all practical purposes and therefore within the claim.

This formulation, the so-called *Catnic* question, formed the basis for claim construction in the UK for the next 20 years, and still underpins the approach.

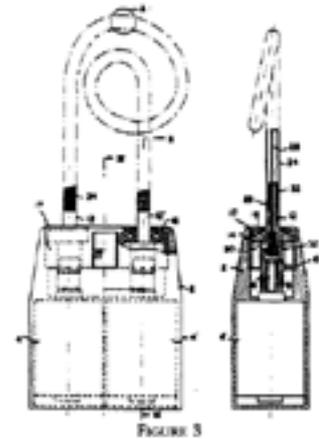
→ The approach under the Protocol – *Improver v Remington*

The first case to consider the infringement of a patent granted under the Patents Act 1977 was *Improver v Remington* [1990] FSR 181. The case concerned Improver Corp's *Epilady* hair removal device (right).

It consisted of a coiled helical spring that was rotated at speed and could be rolled over the body as required. The coils of the spring would therefore open and close like tweezers and trap hairs that were removed by the lateral and cyclic movement of the device.

Remington produced a similar device in which the spring was replaced by an elastomeric rubber rod into which slots had been cut. When bent and rotated, this operated with the same tweezer-like action as the *Epilady*.

Improver's patent claimed a "coiled helical spring". Did Remington's slotted rubber rod infringe?



→ The *Improver* questions

At the interim injunction stage of the proceedings, the Court of Appeal had held that *Catnic* was the correct approach to adopt under the new law. However, when the case came to full trial, the judge considered that Lord Diplock's one question would be better formulated as three. Accordingly, the *Improver* questions were born. These asked:

1. Does the variant have a material effect upon the way the invention works? If yes, the variant is outside the claim. If no -
2. Would this (i.e. that the variant had no material effect) have been obvious at the date of publication of the patent to a reader skilled in the art? If no, the variant is outside the claim. If yes -
3. Would the reader skilled in the art nevertheless have understood from the language of the claim that the patentee intended that strict compliance with the primary meaning was an essential requirement of the invention? If yes, the variant is outside the claim.

→ Application of the questions to the facts

Applying the three questions to the facts, the court held that the substitution of the spring with the slotted rubber rod would not have had any material effect on the way the invention worked – both were bendy and slitty and removed hairs by trapping them in a tweezer-like movement. The first question was therefore passed. Moreover, this would have been obvious at the patent's date of publication. Stage 2 was also passed. However, the case for infringement was to fall at the final hurdle, as the judge considered that the skilled person would nevertheless have considered the patentee to have intended strict compliance with the primary meaning of the claim:

"This is not a case like Catnic in which the angle of the support member can be regarded as an approximation to the vertical. The rubber rod is not an approximation to a helical spring. It is a different thing which can in limited circumstances work in the same way."

It was accordingly outside the scope of the claim.

→ A new approach?

For the next 15 years the *Improver* questions were habitually deployed by the English courts as the correct approach under the Protocol. However, this changed in 2004 with the House of Lords decision in *Kirin-Amgen v Hoechst Marion Roussel* [2004] UKHL 46.

The case concerned a patent for the manufacture of erythropoietin (EPO), a polypeptide which regulates the production of red blood cells. The technology involved was complex, as can be deduced from the parties' agreement that the notional addressee would consist of a team of people, including three PhDs with several years' experience in gene technology, molecular biology and cell biology respectively. It would also include two laboratory technicians well acquainted with gene technology and biochemical techniques, and adequate laboratory facilities to support the team.

Reappraising the current approaches to claim construction, Lord Hoffmann, giving the lead judgment in the House of Lords, considered that in cases of such complexity, the *Improver* questions were actually unhelpful.

→ The approach under *Kirin-Amgen*

Reappraising the law on claim construction, Lord Hoffmann stressed that Article 69 EPC was the key provision (the Protocol, on the other hand, is a “protocol on the interpretation of Article 69, and not on the interpretation of claims”). Article 69, he said, declares that the claims function to clearly delimit the scope of monopoly that the patentee is to enjoy. The claims must be interpreted in context – a purely dictionary-based, acontextual, interpretation is not permissible.

However, “the language [the patentee] ... has chosen is usually of critical importance”. Moreover, the conventions of language, word meaning and syntax enable the expression of meanings with great accuracy and subtlety, and this will be understood by the skilled addressee, who “will assume that the patentee has chosen his language accordingly”.

The key question, therefore, is to ask what the skilled addressee would understand the patentee (i.e. the person drafting the patent) to have used the words in the claim to mean, and not what was going on in the inventor’s mind.

Summary of the UK approach to claim construction

The claims are interpreted in the light of the description and the drawings (Section 125(1) PA 1977; Article 69 EPC).

The test used in the UK is that laid down in *Kirin-Amgen*, i.e. to ask what the skilled addressee would understand the patentee (i.e. the person drafting the patent) to have used the words in the claim to mean.

This is not the same as asking what the skilled person would (himself) understand the words to mean, or even asking “what does this word mean to me?”

Context is critical to the analysis.

The German approach – *Schneidmesser I*

Schneidmesser I (2002) 33 IIC 873, at 875

The German approach to claim construction is exemplified by the *Schneidmesser* ("Cutting Knife") decision of the *Bundesgerichtshof* (Supreme Court). The case concerned a patent for a paper-cutting apparatus that comprised a cutting knife co-operating with a counter knife, which were inclined at between 9 and 12 degrees to each other. In the allegedly infringing article, the blades were inclined at 8°40', i.e. just outside the range.

Approaching the issue of construction, the Court stated that the essential question was whether:

"the skilled person, on the basis of considerations linked to the sense of the invention protected in the claims and by using his specialised knowledge, was able to arrive at the modified means used in the contested embodiment as means having substantially similar effects in terms of solving the problem addressed by the invention."

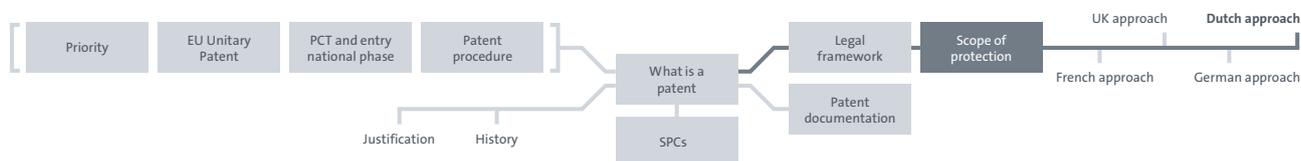
When making this assessment, the claims were not merely a starting point for this analysis, but rather were the "authoritative basis" for doing so.

Nevertheless, if the alleged infringement differs slightly from the claimed invention, i.e. if there is a variant (as in the case before the court) that falls outside the literal meaning of the claim, then the Court considered that the following three questions should be asked:

1. Does the embodiment solve "the problem addressed by the invention with means which, albeit modified, objectively have substantially similar effects?"
If so;
2. Would "the skilled person, as a result of his specialised knowledge ... be able to arrive at the modified means as means having substantially similar effects ... on the basis of the claim?" If yes;
3. Would "the skilled person, considering the technical teaching protected in the claim, understand the differing embodiment with its modified means to be a solution equivalent to that of the patent?"
If so, the equivalent falls within the scope of the patent.

Applying this to the facts, the Court considered that the purpose of angling the blades at between 9 and 12 degrees to each other was simply to ensure a smooth cut. This benefit was also achieved when the angle was slightly more acute. Accordingly, there was infringement.

The Dutch approach (Supplementary reading)



Introduction

Determining the scope of protection of a patent is relevant not only with respect to establishing infringement, but also with respect to assessing validity. The Dutch courts assess actions for patent infringement and counterclaims in which the validity of the patent is contested at the same time in the same proceedings, i.e. there is no bifurcated patent system in the Netherlands.

In the Netherlands, patent cases are exclusively litigated before the courts of The Hague. The district court and the appeals court decide the facts and the law. The Dutch Supreme Court's task is in principle limited to reviewing how the lower court has applied the law, and thus it will not review the facts. The interpretation of a (specific) patent is regarded as a matter of fact by the Supreme Court. However, it has nonetheless repeatedly shed light on how the scope of protection of a patent should be established in general.

The Dutch Supreme Court's approach to the scope of protection of patents

In 1930, the Dutch Supreme Court ruled in the case *Philips v Tasseron* that the law is violated when a judge does not take the essence of the invention ("*het wezen van de uitvinding*") as a starting point for establishing the scope of protection of a patent. This doctrine remained established case law for a long time. Under this approach, it was possible for a judge to accord a broader scope to the patent than would follow from the exact wording of the claims. The determination of the scope of protection on the basis of this doctrine was unchallengeable on appeal before the Supreme Court because of its factual nature.

Supreme Court of the Netherlands, 20 June 1930, *NJ* 1930, p. 1217 with commentary from PS (*Philips v Tasseron*).

See e.g. Supreme Court of the Netherlands 23 June 1972, *NJ* 1972, 451 with commentary from LWH, BIE 1972, 228 (*Fruitsortermachine*); opinion of advocate general Franx at Supreme Court of the Netherlands, 10 June 1983, *NJ* 1984, 32 with commentary from LWH (*Pfizer v Pharmon*).

The Supreme Court's doctrine of the essence of the invention was heavily criticised, because the scope of protection, when determined by applying this doctrine, was not foreseeable by third parties. The legal certainty of third parties was thus at issue, since third parties (i.e. competitors) could

not rely on the substance of the patent claims when determining the scope of protection of the patent.

In 1978, when incorporating changes resulting from the ratification of the European Patent Convention, the Netherlands also adapted its national patent law to the provisions of the Strasbourg Convention. As a result, the Dutch Patent Act 1910 (*Rijksoctrooiwet 1910*) stated in Article 30(2) that the claims determine the scope of protection of a patent and that the description and drawings serve to interpret those claims. The Dutch courts did not, however, immediately align their judgments with the uniform European provisions on the determination of the scope of protection.

Nowadays, this provision is included in Article 53(2) of the Dutch Patent Act 1995.

It was argued that the Dutch approach had to give way to the European provisions on the determination of the scope of protection of European (national) patents. In other words, Article 69 EPC – and not national laws – should be applied when determining the scope of protection.

See Pieroen, Diss. 1988; see also Huydecoper, BIE 1992, 34; Hamaker, *IER* 1994, 161; Wien, *NJB* 1995, 1035; Hoijtink, BIE 1995; Brinkhof, BIE 1995, 6.

It was only in 1995 that the Supreme Court changed its approach as regards the determination of the scope of protection, and then only slightly. In *Ciba Geigy v Oté Optics*, it took, as usual, the essence of the invention as a starting point for establishing the scope of protection of a patent. It then went on, however, to clarify “the essence of the invention” by introducing a new wording, namely “the inventive concept behind the wording of the claims” (“*de achter de woorden van de conclusies liggende uitvindingsgedachte*”). The Supreme Court further acknowledged that application of the doctrine of the essence of the invention does not make any allowance for a reasonable degree of certainty for third parties. For this reason, a court, once it has determined the essence of the invention, must assess whether sufficient justice has been done for the legal certainty of third parties. According to the Supreme Court, a lack of clarity for the average person skilled in the art would justify an interpretation that is more in line with the wording used. However, the extent of the innovation would in turn provide scope for protection extending beyond the actual words of the claims.

Supreme Court of the Netherlands, 13 January 1995, *NJ* 1995, 391 (*Ciba Geigy v Oté Optics*).

In 2007, the Supreme Court made it clear in *Lely v Delaval* that the essence of the invention is not to be considered as a “starting point,” but as a “viewpoint” (“*gezichtspunt*”). In *AGA v Occlutech* (2012) and, more recently, *Medinol v Abbott* (2014), the Supreme Court again mentioned the viewpoints to be taken into account when determining the scope of protection. The effect of the Supreme Court’s use of these viewpoints may not be noticeable in the case law of the lower courts, which does not mention the essence of the invention as an important element in determining the scope of protection of European and national patents.

Supreme Court of the Netherlands, 7 September 2007 (*Lely v Delaval*).

Supreme Court of the Netherlands, 25 May 2012 (*AGA v Occlutech*).

In **Medinol v Abbott**, the Supreme Court also referred to the viewpoints to be taken into account when determining the scope of protection. In this case, Medinol argued that, when determining the scope of protection of a patent, the literal wording of the claims must prevail and that the scope of protection of a patent can (be broadened, but) not be limited by the description and the drawings. According to Medinol, the context of the claims (i.e. the description and the drawings) is of importance only when the wording of the claims is not clear. The Supreme Court ruled that Medinol's argument ignored the fact that Article 1 of the Protocol puts beyond doubt that the scope of a European patent is not exclusively determined by the literal wording of the claims, and that Article 69 EPC should not be construed as meaning that the description and drawings may only serve to eliminate any ambiguities. If from reading the description the skilled man comes to that conclusion, the extent of the protection conferred by the claims can be even more limited than might appear when reading the claims out of context.

Supreme Court of the Netherlands,
4 April 2014 (*Medinol v Abbott*).

Relevance of the prosecution file for determining the scope of protection

Defendants may rely on the prosecution file when arguing the scope of protection. The Supreme Court ruled in **Meyn v Stork** (1989) that third parties may assume that the patentee wanted to limit himself by the chosen wording of the claims, if good reasons existed for that assumption having regard to the patent specification in the light of any other known data, such as the prosecution file.

Supreme Court of the Netherlands,
27 January 1989, NJ 1989, 506, GRUR Int.
1990, 386; IIC 1992, 533 (*Meyn v Stork*),
para. 3.5.

According to the Supreme Court in **Ciba Geigy v Oté Optics** (1995), the prosecution file only plays a role in determining the scope of protection if, after consideration of the description and the drawings, reasonable doubt exists as to the interpretation of the claims. This approach was confirmed by the Supreme Court in **Dow v Stamicarbon** (1997) and **Van Bentum v Kool** (2002).

Supreme Court of the Netherlands,
13 January 1995, NJ 1995, 391 (*Ciba Geigy
v Oté Optics*).

The Supreme Court also ruled in **Ciba Geigy v Oté Optics** that ambiguities which result from an inaccurate formulation are in principle at the patentee's own risk. According to the Court, arguments from the prosecution file in favour of the patentee may be used to a limited extent only. The defendant in infringement proceedings, however, may always derive arguments from the prosecution file.

Supreme Court of the Netherlands,
5 September 1997, BIE 1998, 85 (*Dow v
Stamicarbon*) and Supreme Court of the
Netherlands, 29 March 2002, RvdW 2002,
64 (*Van Bentum v Kool*).

In **Saier v Dijkstra** (2006), the Supreme Court ruled that third parties are not limited to using arguments based on the prosecution file.

Supreme Court of the Netherlands,
22 December 2006, RvdW 2007/25 (*Saier
v Dijkstra*).

Indirect infringement

The patentee may enforce its patent against any party which, in or for its business, offers or supplies means relating to an essential element of the patented invention to parties which are not entitled to use the patented invention (Article 73 Dutch Patent Act). A patent is infringed only when both the offering or supplying and the application of the invention take place in the Netherlands. It does not matter whether the means relating to an essential element of the patented invention are offered or supplied from the Netherlands or from abroad. Furthermore, the party supplying the means must know that those means are suitable and intended for application of the patented invention, or that such is evident in view of the circumstances.

Pres. District Court The Hague, 13 December 1988, BIE 1991, 135 (*mixers*);
Pres. District Court The Hague, 8 September 1998, BIE 1999, 244 (*Rustibus*);
Court of Appeal The Hague, 30 March 2010, I 2010, 70 (*Van Beelen v Otter*).

In the case *Sara Lee v Intergro* (2003), the Supreme Court decided that the mere necessity of a certain element for the purposes of the invention does not in itself render it essential to the patented invention: the relevant feature must, in addition, distinguish the invention from the prior art.

Supreme Court of the Netherlands, 31 October 2003, BIE 2004, 47 with commentary from JdH (*Sara Lee v Intergro*), para. 3.4.2.

Equivalence

The Dutch courts also take into account infringement by way of equivalence. In the event that a product or process does not fulfill one or more features of a patent claim, the court will establish whether or not the product or process contains equivalent measures.

Following on from the Supreme Court's decision in *Dreizler v Remeha* (1995), the Dutch courts usually apply the so-called "function-way-result test". In patent cases relating to chemical inventions, the lower courts may also apply the "insubstantial differences test" or assess whether it is "obvious to a person skilled in the art that substantially the same result as that achieved by means of the element as expressed in the claim can be achieved by means of the equivalent element." In this test, the court assesses whether a difference between a product (or process) and a claim is material.

Supreme Court, 13 January 1995, NJ 1995, 392 (*Dreizler v Remeha*).

See District Court The Hague, 28 October 1998 (*Yamanouchi v Biogen*).

In its decision in *Stamicarbon v Dow* (1998), the Supreme Court acknowledged that a product or process could fall within the scope of protection of a patent by way of equivalence, but ruled that equivalence does not pertain where application of the alleged infringing process leads to a significantly inferior result.

Supreme Court of the Netherlands, 5 September 1997, BIE 1998, 85 (*Stamicarbon v Dow*).

The lower Dutch courts have become very reluctant to accept equivalence, since more and more attention is being paid to legal certainty for third parties. In recent years, there have been hardly any cases where the lower courts have accepted infringement by way of equivalence. Furthermore, it has been held in lower-court decisions that inventive variants, i.e. products or processes which are protected by an independent patent, cannot be considered equivalents.

The most recent patent cases where the Dutch courts accepted infringement by way of equivalence are: District Court The Hague, 31 March 2010 (*Ezendam v Lommers*), para. 4.23, District Court The Hague, 2 July 2008 (*Novartis v Actavis and Pharmachemie*), para. 4.99, Court of Appeal The Hague, 24 May 2007 (*Air Force v Smillie*), para. 15-16, and Court of Appeal The Hague, 23 February 2006 (*Multifase Schroef-spilpomp*), para. 33. In the latter case, however, the Supreme Court decided (25 April 2008) that the Court of Appeal's judgment as regards infringement by way of equivalence could not be upheld, since the Court of Appeal, contrary to Article 24 of the Dutch Code of Civil Procedure, complemented the factual basis of the defendant's infringement claim (para. 4.4.1–4.5).

Date at which the claims must be interpreted for the purpose of infringement proceedings

The Supreme Court ruled in *Medinol v Abbott* (2014) that, when determining the scope of protection of a patent, the knowledge of the skilled person at the filing date or priority date serves as a guide. Within the framework of establishing infringement, in addition to the knowledge of the skilled person on the filing or priority date, significance can also be attached to the knowledge of the skilled person at the infringement date, especially when infringement by way of equivalence has to be assessed.

Supreme Court of the Netherlands, 4 April 2014 (*Medinol v Abbott*), para. 3.5.2.

Defences to infringement

In the Netherlands, the research exemption is laid down in Article 53(3) DPA. This article states that acts serving solely for research on the patented subject-matter, including the product obtained directly as a result of using the patented process, do not infringe the exclusive right of the patent owner.

Research exemption: Article 53(3) DPA

According to the legislative history of the Dutch Patent Act, this research exemption must be interpreted restrictively. It is designed only for acts that serve exclusively for investigating the patented invention. It follows from the doctrine and case law that only research having a purely scientific character is considered to fall under the research exemption. Market research or large-scale manufacture is not allowed. Performing clinical trials within the context of obtaining market authorisation for a generic medicinal product does not fall under the research exemption either.

Kamerstukken 2005–2006, 30 663 (R 1812), nr. 3, p. 3.

Supreme Court, 18 December 1992, IER 1993, 17, BIE 1993, 310, (*Medicopharma v ICI*); Supreme Court, 23 June 1995, BIE 1997, 235 (*ARS v Organon*); District Court The Hague, 17 January 2007, BIE 2007, 474 (*Conor v Angiotech*).

The Bolar exemption set out in Article 10(6) of Directive 2001/83/EC (as amended) was implemented in Article 53(4) DPA. This provision states that conducting the necessary studies, tests and trials within the context

Bolar exemption: Article 53(4) DPA

of obtaining market authorisation for a generic medicinal product (hybrid generics and biosimilars included) is not to be regarded as contrary to patent rights or to supplementary protection certificates for medicinal products.

Article 53(4) DPA refers to the studies, tests and trials that must be performed in order to obtain marketing authorisation for either of the generic medicinal products referred to in Article 10(1-4) of Directive 2001/83/EC (i.e. “true” generics, hybrid generics and biosimilars). This means that both the bioavailability studies which are required within the context of true generic applications and the preclinical tests and clinical trials which are required within the context of hybrid applications and biosimilar applications are permitted to be performed. Such studies, tests and trials are hence not considered to infringe the exclusive rights of a patentee. There is no Dutch case law specifically dealing with the Bolar exemption.

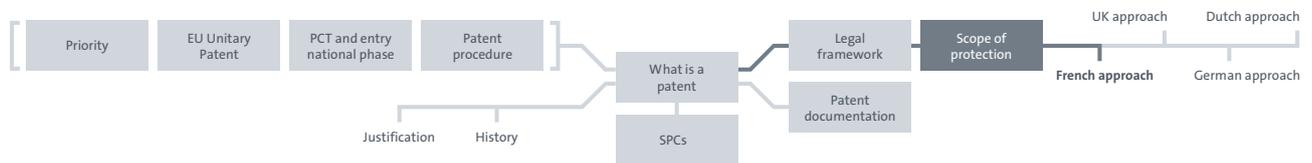
If a challenged product belongs to the prior art, or is a non-inventive variant of that art, it cannot infringe a later patent. After all, a patent cannot be interpreted such that the prior art falls within the scope of protection: the patent would then be (partially) invalid. This fundamental principle was first clearly formulated by Lord Moulton of the British House of Lords in 1913, in *Gillette v Anglo American Trading Company*, and has since been known as the “Gillette defence”.

House of Lords, *Gillette v Anglo-American* [1913] 30 RPC 465.

The Gillette defence is acknowledged by the Dutch courts. In Dutch proceedings, it may also be applied in cases of alleged “literal” infringement – i.e. equivalence is not a condition. Examples of Dutch case law in which the Gillette defence played a role are *SKB v FAL Duiven* (2006), *Fort Vale v Pelican* (2007), *MSD v Generieken* (2008) and *B+R v Van den Berg* (2010).

District Court The Hague, 22 March 2006, BIE 2006, 83 (*SKB v FAL Duiven*), para. 4.20, District Court The Hague, 30 May 2007, IEPT 20070530 (*Fort Vale v Pelican*), para. 4.19–4.21, District Court The Hague, 13 February 2008, IEPT 20080213 (*MSD v Generieken*), para. 5.14, and District Court The Hague, 27 April 2010, IEPT 20100427 (*B+R v Van den Berg*), para. 4.12.

The French approach (Supplementary reading)



France has always been known for having a patent-friendly concept of infringement.

In a nutshell, the main step for the court is to determine whether the claimed means differ from the prior art by a novel form (or structure) (“particular means”) only, or by a novel function (“general means”).

This distinction is intended to prevent disguised infringement.

Claim construction

French patent construction is purposive, to give the claim its full meaning and to define the substance of the claimed invention.

Construction of the specification and claims is usually discussed in the first part of French judgments, under the heading “Scope of the patent”.

Claim construction is governed by Article 69 of the European Patent Convention for European patents for which France is a designated state and Article L. 613-2 of the French Intellectual Property Code for French national patents. These two articles, which are identical, state that “*the extent of the protection conferred by a patent shall be determined by the claims*” but that “*nevertheless, the description and the drawing shall be used to interpret the claims*”.

The French approach remains as defined by a decision issued by the Court of Appeal of Paris on 11 October 1990 in the first case involving a European patent (*Dolle v Emsens*):

“Article 69, as completed by its protocol, has chosen a middle way between a literal construction of the claim, in which the description and the drawings should be used only to dissipate ambiguities, and a broad construction, in which the claim would be used just as a guideline and in which the protection would extend to what, according to the skilled person, the patentee intended to protect.”

This compromise must ensure a fair protection for the patentee against the skill of the infringer to disguise infringement, and enable third parties to know with certainty what is protected.

In view of Article 69, the judge must construe the claims by reference to the description and drawings.

He must give the claim its full meaning, so that this condensed text is understood.

The construction leads to a definition of the substance of the claimed invention, without adding any element which the claim did not include and did not suggest.”

The reference to the full meaning of the claim and the substance of the invention shows that French judges seek a fair balance to ensure both reasonable protection for the patentee and a reasonable degree of legal certainty for third parties.

When construing claims, they seek to understand, with the eyes of the skilled person, the technical problem solved by the patent and the means taught to solve said problem, including their function.

However, the construction of a claim must not result in the addition of a feature which it does not include (*“interpreting is not adding”*) or, conversely, in the omission of a feature which it comprises.

When seeking to understand a patent, judges may take account of any definitions contained in dictionaries, handbooks or other documents submitted by the parties, but these definitions must never prevail over the meaning stemming from the patent itself.

Any such documents submitted are used mainly to help clarify, where necessary, the knowledge of the skilled person and the way they would read and understand the patent.

A written expert opinion may be provided if required in order to further clarify the documentary evidence and substantiate the knowledge of the skilled person, although this is not usual.

These tools will, where appropriate, also help judges to distinguish between:

- The features which should be considered “essential”, i.e. those without which the claim would not be considered novel and inventive or without which the claimed means would not perform the function of the invention, and

- The features which should be considered as minor (i.e. details), because they are not necessary for the claim to be novel and inventive and not indispensable for the claimed means to perform their function.

The key idea is to understand the extent to which the means taught by the patent differ from the prior art, in other words whether it is by some details of structure (or form) or because they perform a new function.

Claim construction is partly a question of fact and partly a question of law.

The *Cour de cassation* (France's highest civil court) checks the legal reasoning of the *cour d'appel*, but not its factual findings.

As a result, it will quash decisions showing that the construction exercised led to a distortion of the claim (by either the addition or omission of a feature) or to the creation of a contradiction between the specification and the claim.

But it will not review the technical findings of the *cour d'appel* about the knowledge of the skilled person.

The claims and specification are construed at the date of filing or priority date (where applicable) of the application.

The scope given to the claims is the same for both validity and infringement, so the so-called **Angora cat paradox** (see right) cannot apply.

The **Angora cat paradox** refers to the opposite approaches adopted by some patentees during prosecution and litigation. During prosecution, the claims are presented as being as narrow as a wet Angora cat to better distinguish them from the prior art. Once granted, however, and for the purpose of an infringement case, the same claims become far broader, like an Angora cat with thick, dry fur.

The person skilled in the art and his general knowledge

The person skilled in the art has no place in the assessment of infringement under French law, in particular because the question of whether the contested product was an obvious alternative is not relevant.

However, the person skilled in the art and his knowledge *are* taken into account for the construction of the claims and specification.

In any case, the skilled person is the same for all purposes relating to the same patent.

This person is a pure legal fiction. Professor Jean-Marc Mousseron defines him as *“a notional average person skilled in the art with access to a vast amount of documentation but with reasoning abilities limited to those of an average skilled person with no inventive capacity and no ability to go beyond the obvious area surrounding his knowledge”*.

“Technicien moyen étrange, il accède à une documentation considérable, mais ses facultés de raisonnement sont limitées à celles d’un agent moyen sans la moindre capacité inventive, sans la moindre aptitude à dépasser la zone d’évidence qui entoure les connaissances qu’il maîtrise.”

Professor Jean-Marc Mousseron, *Traité des brevets, Librairies techniques*, 1984, page 398

Since around 2009, French judges rarely omit to define the field and skills of the skilled person. He is usually the manufacturer, and not the user, of the claimed product.

In cases where the technical problem solved by the patent involves several technical fields, the skilled person may also be a team. For example, the decision of the *Tribunal de Grande Instance de Paris*, 3rd chamber, 3rd section, of 25 March 2009 (*Novartis v Johnson & Johnson*) held that:

“The person skilled in the art is a team made up of a polymer chemist whose objective is to develop suitable materials, a physicist in charge of determining the physical properties of the lenses and a clinician ophthalmologist specialising in contact lenses.”

The skilled person is defined as a specialist of average qualification or capacity in the field concerned. This can lead to considering an average technician for a relatively simple technical field and a highly qualified specialist in more complex cases.

The knowledge of the skilled person includes all the knowledge of his technical field, the knowledge of neighbouring fields raising identical or similar problems, general knowledge which is not specific to the relevant field (for example general mechanical knowledge), and common sense. It does not include research data which has not yet been validated. It may be supported by documents, and occasionally by a party’s expert opinion on documents submitted by the parties.

The skilled person has the ability to make logical deductions and perform routine operations and implementation work.

The French tests for infringement

The philosophy behind the purposive construction leads French judges to a relatively broad concept of infringement by equivalence, as set out in Pierre Véron's article "*France v The rest of the world*".

"Doctrine of Equivalents, France v The rest of the world" by Pierre Véron, Patent World, November 2001

Paul Mathély defines infringing means as those means which reproduce the essential means of the claimed invention, i.e. the novel and inventive means brought by the patent to the art which are necessary and sufficient to perform the function of the claimed invention.

"Les éléments constitutifs de l'invention sont les moyens, nouveaux et inventifs, que le brevet apporte à la technique antérieure, et qui exercent la fonction qu'il a prévue."

Ces moyens sont essentiels, lorsqu'ils sont nécessaires et suffisants pour assurer l'exécution de cette fonction ; les moyens essentiels sont ceux qui forment la substance de l'invention, et qui sont la condition même de la fonction qu'elle exerce."

This broad approach is supported by the traditional view that infringement is assessed by similarities and not by differences.

"Le nouveau droit français des brevets d'invention" by Paul Mathély, chapter II, section 1, page 413

The French infringement test can be considered as three-fold:

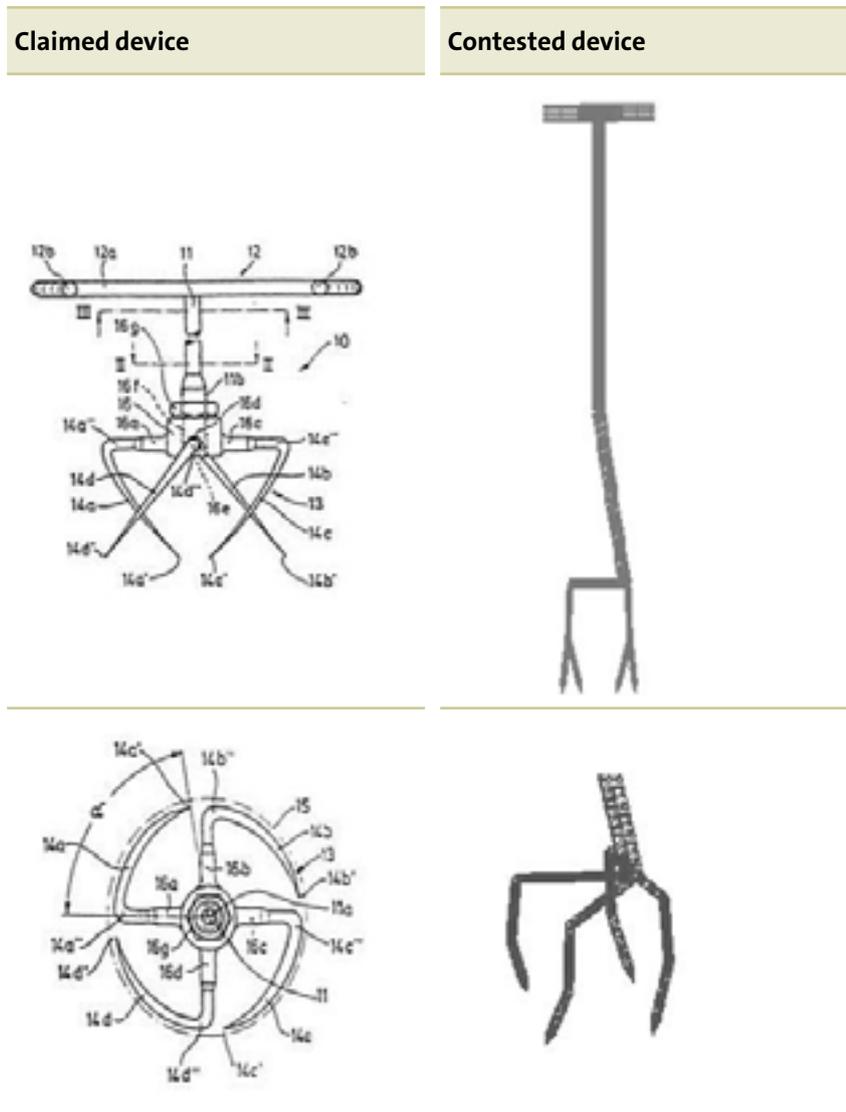
- (i) The first question is whether there is **literal infringement**, i.e. whether the contested means reproduce the claimed means in both their form (or structure) and function.
- (ii) If not, the second question is whether there is **infringement by reproduction of the essential means of the claim**, which is answered in the affirmative if the differences between the claimed and the contested means relate only to details and not to essential means of the claim.
- (iii) If not, the third question is whether there is **infringement by equivalence**, which is the case if the claimed means perform a new function and if the contested means perform said function for the same results as the claimed means.

Tribunal de Grande Instance de Paris, 3rd Chamber, 1st section, 26 April 2000 (Garden Claw v Leborgne)

For each of these steps, both the claimed and the contested means should be considered not only in terms of form (or structure), but also in terms of function (meaning the primary technical effect) and results (meaning the advantages provided by the invention).

The way infringement is tested in France is illustrated below using the example of a claim covering a gardening device.

The figures show the claimed device and the contested device.



The patent at issue relates to a manual gardening device, comprising a handle at one end and a tool at the other, for loosening soil, mixing soil layers and removing weeds without great effort thanks to a helical movement.

Claim 1 relates to the structure of the tool, and in particular the arrangement of its tines, in which the tines:

- envelop a virtual cylinder in the axis of the shaft, and
- form an angle of approximately 90°.

On the basis of the explanation provided by the description, the Court considered that the function of the device was to rotate so that it could be introduced into the soil in the manner of a screw and thereby loosen the soil and mix its different layers.

Claim 1

A manual agricultural implement, comprising a shaft (11), a handle (12) arranged on one end of said shaft and a tool on the other end of said shaft and including a plurality of helically curved tines (14) disposed around said shaft (11) in a radially spaced relationship therewith, characterized in that said tines (14a – 14d) extend parallel to each other along an imaginary cylinder (15) which is coaxial to said shaft (11), and that said tines (14a – 14d) are evenly distributed over the circumference of said imaginary cylinder (15) and curved such that the lines which connect the tine feet (14 a'' – d'') and tine tips (14 a' – 14 d') with the axis of said shaft (11) form an angle of approximately 90°.

Literal infringement

Literal infringement (“*contrefaçon à l’identique*”) occurs when the contested means reproduce the claimed means in their form and function for the same result.

However, in most cases, the contested means are not identical to the claimed ones.

In the gardening device example, the contested device did not reproduce the claimed means in their form and function for the same result, since there was a notable difference relating to the angle formed by the tines (90° in the patent, but far smaller in the contested device).

Far from excluding infringement, the existence of differences leads to the second step of the infringement test, which is to determine whether these differences relate to details or to essential means of the claim.

Infringement by reproduction of the essential means of the claim

According to some decisions and legal writers, infringement by reproduction of the essential means is included in literal infringement. Infringement by reproduction of the essential means of the claim is deemed to exist when the differences shown by the contested means relate only to details, in other words minor features.

There are two aspects to this:

- First, comparison of the claimed means and infringed means allows you to determine the features of the claim which are not reproduced, which is quite easy.
- Second, you have to determine whether the non-reproduced features constitute details only (in which case there is infringement), or whether they constitute essential means of the claim (in which case it will be necessary to apply the third part of the infringement test to decide whether there is infringement).

French decisions show the various questions which should be examined to determine whether a feature is a detail or an essential feature of the claim:

- Is the feature presented as essential in the patent or during the pre-grant prosecution phase? For example, does the patent mention alternatives?
- Is it one of those without which the claim would not have been found novel and inventive?
- Is it indispensable for fulfilling the function of the claimed means and solving the technical problem underlying the invention?

The question as to whether the patent mentions alternatives appears in a decision of the *Tribunal de Grande Instance de Paris*, 3rd chamber, 4th section, of 28 March 2013 (*somfy v Gaposa*). The fact that the patent gives a precise description of the form of the brake, without mentioning any alternative, is considered as showing that this feature is essential: “*L’invention n’envisage qu’un seul type de frein... sans autre alternative. Il ne peut donc être considéré que cet élément de la revendication du brevet n’est pas essentiel*” (“*The invention considers only one type of brake ... with no alternative. Therefore, it cannot be considered that this feature of the claim is not essential.*”)

If the claimed means which are not literally reproduced turn out to be a minor feature (i.e. a detail), there will be a final finding of infringement.

Otherwise, the analysis continues in order to determine whether there is infringement by equivalence.

When applied to the example of the gardening tool, this two-fold test leads to the following conclusion:

The contested device differs from the claim in particular in that it has tines forming angles of less than 90°. This angle of 90° was not a minor feature, in particular because it was important during prosecution to obtain the grant of the patent and because it is indispensable for the rotation of the tool in the soil like a screw. As a result, it is an essential feature, and the contested device does not constitute infringement by reproduction of the essential features of the claims.

This leads to the last part of the infringement test, which is to determine whether there is infringement by equivalence.

Infringement by equivalence

There is infringement by equivalence when means which do not reproduce the claimed means in their form (or structure) perform the same function for the same results.

However, the doctrine of equivalence applies only if it has been already been ascertained that said function of the claimed means is novel.

The test for infringement by equivalence is therefore three-fold:

- Do the essential means of the patent whose form is not reproduced (“the means at issue”) **perform a novel function?**
- If so, do the contested means **perform the same function?**
- If so, do these contested means **provide the same results?**

Tests applied in some other countries, such as whether it is **obvious to the skilled person** that the contested means are equivalent or what the intention of the patentee was, are not relevant in France.

In a decision of the *Tribunal de Grande Instance de Paris* of 29 September 2004, 3rd chamber, 1st section (*L'Oréal/Al Khouri*), the judges examined the technical importance of the modified means. In this case, the use of the polymer selected by the defendant changed all of the chemical reactions involved in the formation of the capsules:

“... therefore, there cannot be an infringement, since the defendants' process is based on a polymer while the claimant's process involves no polymerisation chemical reaction.

[...] the CNRS patent, used by the defendants, uses a polymer that dissolves in organic phase leading to a solution polymer which, after injecting the solution, precipitates at the surface of the oil nanodroplets also leading to nanocapsules;”.

These explanations refer to cases in which only one of the claimed means is not literally reproduced. However, they also apply when the differences relate to several different means.

The claimed means at issue must perform a novel function

The function is claimed *per se*, because in such cases, any means which perform this function will be held to be infringing, whatever their structure may be. In this case, the infringement is literal.

As a result, the doctrine of equivalence is relevant only for claims which protect one or more means characterised at least partly by their form (or structure).

For these claims, the doctrine of equivalence applies only if the claimed means at issue perform a novel function.

In other words, infringement by equivalence can exist only if the claimed means at issue differ from the prior art not only by their form (or structure) but also by the function they perform.

In yet other words:

- If the function of the claimed means at issue is known in the prior art, then the scope of the claim is limited to the claimed structure (and its minor variants). In this case, the claim is said to cover specific means (“*moyens particuliers*”), and infringement by equivalence cannot apply.
- If the function of the claimed means at issue is novel, the scope of the claim extends to structures performing the same function for the same results. In this case, the claim is said to cover general means (“*moyens généraux*”), and the doctrine of equivalence can apply.

The above explanations show that, when assessing infringement by equivalence, the key question is the contribution of the invention to the art.

This rule has been applied by French judges for decades, and is still being applied, as illustrated by the following recent decisions.

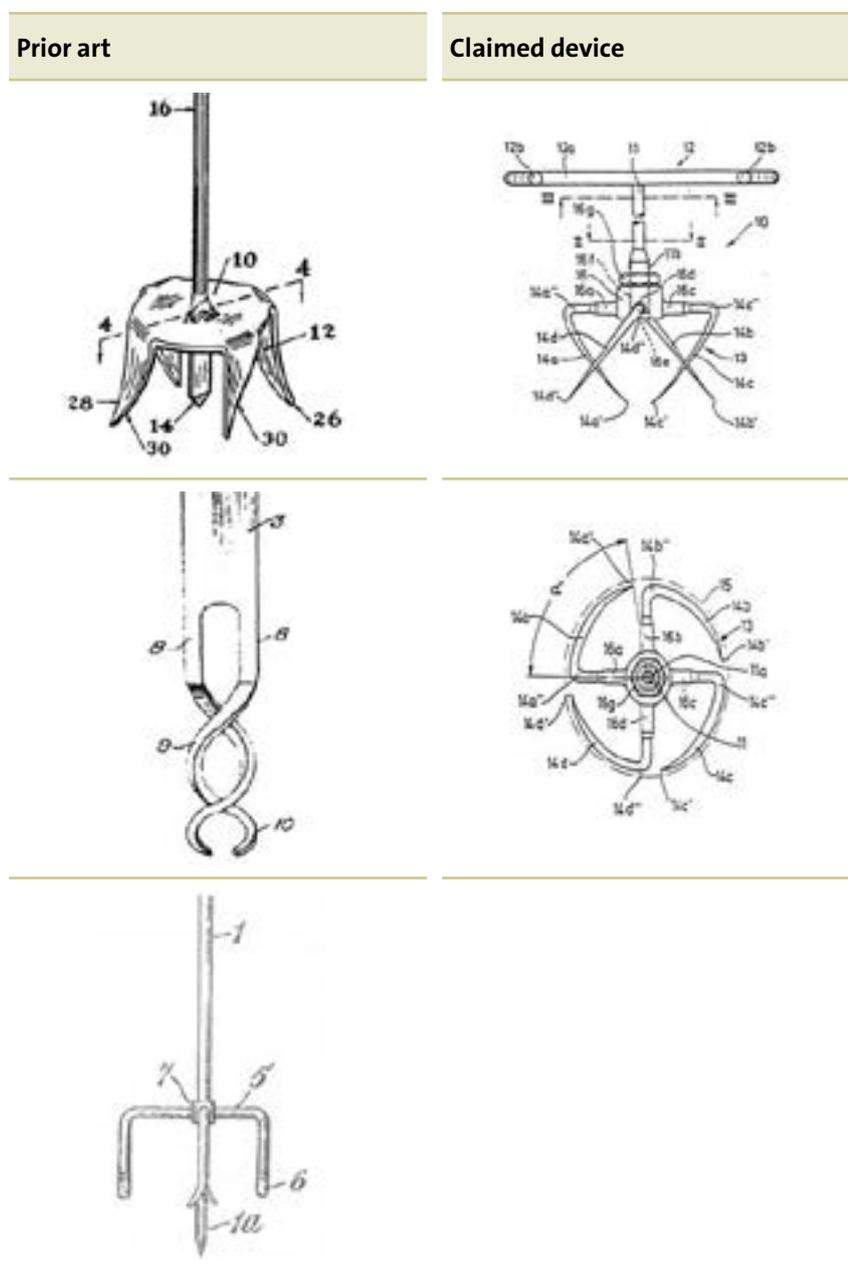
In a decision of 16 April 2013 (*Cycles Lapierre v Decathlon*), the *Cour de cassation*, commercial chamber, held that the appeal judges did not need to determine whether the contested means were equivalent to the claimed means, because they had found that the claimed combination of means differed from the prior art only by their form, and not by their function, which was not new.

Likewise, the *Cour d’appel de Paris*, Division 5, Chamber 1, in a decision of 26 September 2012 (*Beaba v Seb France*), held that there was no infringement by equivalence because the claimed cooking device was an innovation only in the combination of its structural features.

The same approach was followed by a decision of the *Cour d'appel de Paris*, Division 5, Chamber 2, of 17 June 2011 (*Salomon v Merrell and Wolverine*), which considered that the clamping organ of the claimed shoe device could be protected only in the form defined by the claim, because the function performed by this organ was not novel.

These recent decisions are consistent with established French case law. In the example of the gardening device, the question of whether the claimed means (and, in particular, the tines with an angle of 90°) implemented a novel function led the court to study the prior art cited by the alleged infringer and examine whether this specific angle of 90° created a structural difference only, or a functional one, over the prior art.

The drawings below show the claimed device and three gardening tools from the prior art:



The court considered that the function of the 90° angle in the claimed device, i.e. enabling it to rotate like a screw in the soil and loosening the soil, was not disclosed in the prior art.

Therefore, the function of the claimed device, in particular of its angle of 90°, was novel.

When a claimed feature which is not literally reproduced performs a new function, the judges have to proceed to the next part of the test, to determine whether the disputed means perform said function.

The contested means must perform the same function

Two means perform the same function if they produce the same primary technical effect.

The “primary technical effect” can be defined as the effect directly and immediately produced by implementation of the means.

It must not be confused with the result, which is the advantage provided by the means.

Dossiers Brevets 1993, I, 2

This distinction between function and result is particularly well explained in a decision of the *Cour de cassation*, Commercial chamber, of 26 January 1993, involving a patent for a process for obtaining doxycycline through hydrogenation of methacycline, with a modified catalyst.

The alleged infringer argued that the function of the process was to reduce, through hydrogenation, methacycline into doxycycline, which was not novel. The patentee argued that the function of the process was rather to obtain selectivity and stereospecificity at almost 100% of the required epimer (a), which was novel.

The *Cour de cassation* confirmed the judgment of the *Cour d'appel de Paris*, which had decided that obtaining a very high yield of epimer (a) was a novel function, not a result.

As the process carried out by the defendant involved not only the known result of reduction through hydrogenation of methacycline into doxycycline, but also the novel function of selectivity and stereospecificity of epimer (a), the defendant was found to be infringing the patent.

In the example of the gardening device, the question whether the contested device performs the same function for the same result led the court to a finding of non-infringement. It considered that the tines of the contested device did not perform the same function as those of the claim

because they did not have the screw effect. The contested device had to be introduced into the soil through vertical pressure applied by the foot. On the other hand, when the contested means perform the same function as the claimed means at issue, it remains to be assessed whether they achieve the same result.

The contested means must provide the same result

Until recently, French case law considered that the result obtained by the means at issue had to be similar, without necessarily being identical. As a consequence, the result could be of a different quality (less perfect, or better or poorer) or of a different degree than the result obtained by the patented means.

However, some recent decisions have indicated that the result must be “of the same nature and of identical quality and efficacy”.

Tribunal de Grande Instance de Paris, 3rd chamber, 1st section, 3 April 2014, Équipement pour l’environnement v Rabaud, and Tribunal de Grande Instance de Paris, 3rd chamber, 3rd section, 22 November 2013, Manitou v Haulotte

Irrelevant factors (obviousness and the intention of the patentee)

Under French law, obviousness is not a criterion for infringement, but only a ground for invalidity. It is taken into account in the assessment of inventive step only.

Therefore, when assessing whether they constitute infringement by equivalence, the question of whether the contested means are obvious for the skilled person is not relevant in France.

The lack of relevance of obviousness is confirmed by the French approach that improving the claimed means may be an infringement.

This solution used to be referred to as “*improving is infringing*”. However, this does not mean that any improvement of a claim would be an infringement. It only means that an improvement will not automatically avoid infringement and that the infringement test must be applied as usual. Lastly, equivalence is assessed in a purely objective manner, so that there is no reason to speculate about the possible intentions of the patentee.

For example, the decision of the *Tribunal de Grande Instance de Paris* of 29 September 2004 (*L’Oréal v Al Khouri*) recalled that obviousness is not taken into account: “*That it does not matter much, concerning the discussion on the infringement, that the skilled person can replace – based on Mr Al Khouri’s patent – the alkyl monomers by polymers, since this criterion is only relevant, as pointed out by the defendants, for assessing the inventive step of a patent and therefore its validity and not for deciding whether there is an infringement or not*”.

A recent example of infringing improvement is provided by the decision of the *Tribunal de Grande Instance de Paris*, 3rd chamber, 3rd section, of 22 November 2013 (*Manitou v Haulotte*).

However, when the patent explicitly and unambiguously excludes a variant from its scope, this variant, if exploited by a third party, will not be held to be equivalent to the patented invention.

In the same way, when the variant directly and unambiguously goes against the teachings of the patent, it will not be held to be equivalent. Some French decisions do not explicitly describe each of the above steps, and may use a slightly different wording.

Is there a doctrine of file wrapper estoppel?

Estoppel does not exist as such under French law, and judges are under no obligation to refer to the “file story” of the patent, as underlined, for example, in a decision of 23 November 2010 of the *Cour de cassation*, commercial chamber (*Institut Pasteur v Chiron*).

However, it is not uncommon to find decisions which take account of explanations or amendments made by the patentee during prosecution or opposition proceedings.

Some of these decisions refer to the general procedural rule, based on the parties’ duty of loyalty, that a party cannot contradict itself within the framework of the same proceedings to the detriment of another party. However, the application of this general rule is quite limited:

- It applies mainly in cases of a contradiction within the framework of the same proceedings, so that a contradiction with an argument raised in parallel proceedings has less impact (see, for example, *Tribunal de Grande Instance de Paris*, 3rd chamber, 3rd section, 29 June 2012, *LPG Systems v Gianffranco Tudo*).
- It applies only in cases of a real contradiction with regard to the goal pursued (e.g. invalidity claim vs. clear recognition of the validity), whereas a change in the line of argument does not suffice to characterise a contradiction (*Cour d’appel de Paris*, division 5, chamber 1, 19 April 2013, *Recycl’air v Faurecia*).

Independently of the above rule, the content of the “file story” may be taken into account like any other fact of the case. It is up to the judges to assess the possible relevance and impact of the statements and amendments made by the patentee, either during prosecution of the patent application or during opposition.

This is illustrated by the decision of the *Tribunal de Grande Instance de Paris*, 3rd chamber, 2nd section, of 28 May 2010 (*Institut Pasteur v Siemens Healthcare Diagnostics*) (relating to the same patent as the above-cited decision of the *Cour de cassation* of 23 November 2010):

“Institut Pasteur rightly argues that only these provisions [Article 69 and its Protocol] govern the interpretation of the claims’ wording and that the “file wrapper estoppel” theory, which consists in also taking into account, to interpret a patent, the statements made by the applicant during the grant or opposition proceedings, cannot be applied [...]

“Secondly, although pursuant to Article 69 of the Munich Convention in its version applicable to this case and L. 613-2 of the French Intellectual Property Code, the scope of the protection conferred by a patent is determined by the claims as amended following the opposition procedure, and the drawings and the description shall be used to interpret the claims, the cour d’appel, by pointing out that the patent application had been initially filed with 24 claims but that, following the opposition procedure, it had been granted with 11 claims of a limited scope, simply appraised the scope of the claims in their final drafting; the cour d’appel, which did not have to proceed via the allegedly omitted research targeted by the fourth branch of the argument, legally justified its decision.”

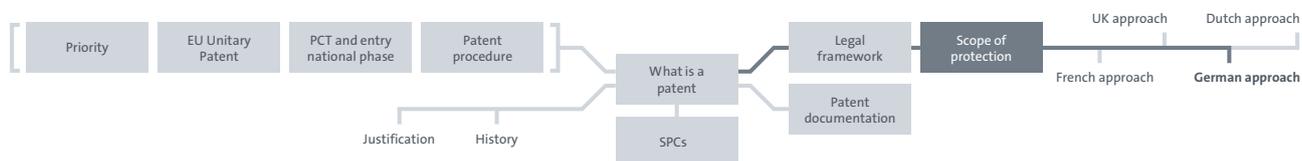
Decision of 23 November 2010 of the *Cour de cassation*, commercial chamber (*Institut Pasteur v Chiron*)

However, they in no way exclude the possibility for the court, which has to rule on the extent of the protection conferred by the patent, of referring to the wording of the claims as initially filed and of appraising the scope thereof, in particular in light of the amendments made during the grant or opposition proceedings before the European Patent Office.”

The discretion of the judges is also illustrated by a case decided by the *Tribunal de Grande Instance de Paris*, 3rd chamber, 2nd section, 1 June 2012, *Le Roy v Saertex*. The defendant, claiming invalidity of the French priority patent on the grounds that it extended beyond the content of the application as filed, relied on the observations of the European Patent Office concerning the equivalent European patent application and was followed by the court. The Tribunal recalled that observations made during the opposition proceedings were not binding, but that reference to these proceedings in the specific scenario of the case was relevant, and admitted the invalidity argument raised by the defendant.

As a result, French case law comprises a significant number of decisions using the file story of the patent to clarify issues arising in constructing the patent.

The German approach (Supplementary reading)



Claim construction

According to both **Article 69** of the European Patent Convention (EPC) and **Section 14** of the *Patentgesetz* (German Patent Act) (PatG), the scope of protection conferred by a patent is determined primarily by the claims. The description and drawings have to be considered when construing the claims, but they can never extend or restrict the scope of protection (on their own). This means two things:

- A technical teaching is not protected if it can only be found in the description or drawings but not in the properly construed claim.
- The scope of protection as derived from the claims is not restricted by a narrower description or a particular drawing. In particular, the scope of protection is not restricted to the examples or to a preferred embodiment as described in the patent.

There are many ways in which the description and drawings can be relevant when it comes to construing the claims. First, the general assumption is that the claims, description and drawings form a unit which is consistent in itself. Therefore, whenever the claim language permits, it would be preferable to construe it in such a way that all those embodiments which are described as being “according to the invention” are indeed covered by the claims. The *Bundesgerichtshof* (German Federal Court of Justice, BGH) has said that it is not completely impossible for claims to be (or become, in invalidity proceedings) restricted in such a way that they no longer cover any of the examples given in the description.

Claims are construed in the way that a notional person skilled in the art would understand them. Individual terms will often simply have an “ordinary” meaning as generally known to a person skilled in the field of technology concerned, or as can be found in a dictionary. But if the patent provides or requires a specific definition, this will overrule the standard definition.

Relevance of claims, description and drawings

The claims are what matters when it comes to determining the scope of protection. The description and drawings are helpful in construing the claim language, but on their own they neither extend nor restrict the scope of protection as derived from the properly construed claims.

BGH, GRUR 2015, 159-167 – “Zugriffsrechte”

In a conflict between extrinsic evidence (definition given in a standard dictionary) and intrinsic definition (definition in the patent itself) the intrinsic definition prevails

Such specific or “unconventional” definitions can result from an explicit definition in the claims or description. The BGH has made it clear that patentees are allowed to act as “their own lexicographer”.

Patentees can be their own lexicographer
BGH, (1999) 30 IIC 932 – X ZR 85/96
“*Spannschraube*”

Even where there is no explicit definition in the patent, claim terms can have a meaning that deviates from the “ordinary” meaning or from the meaning that the same term has in the prior art. The person skilled in the art will prefer to give claim terms a meaning such that the technical function of each term is properly reflected, including within the context of the other claim terms. This is commonly referred to as “purposive construction” or “functional claim interpretation”. However, in respect of features which are spatially and physically defined in the claims, purposive construction does not allow such features to be reduced to their technical function. They cannot be freed from any spatial or physical definitions given in the claims. Otherwise, the boundaries between literal and equivalent infringement (see below) would become blurred.

Purposive construction or functional claim interpretation
BGH, (1999) 30 IIC 932 – X ZR 85/96
“*Spannschraube*”

Another aspect in claim construction is that certain terms may be associated with a specific meaning that is unique to patent publications. For example, a claim using “comprising A + B” language should generally be construed as being open to the addition of further constituents which are not expressly listed (that is, the expressly listed constituents A and B do not have to add up to 100%), whereas a claim using “consisting of A + B” language should generally be construed as giving an exhaustive list of constituents (that is, the expressly listed constituents A and B should add up to 100%).

Particular meaning of terms in patent matters
Case Law of the Boards of Appeal of the European Patent Office, 7th ed. 2013, at II.A.6.2 (p. 267);
BGH, GRUR (2011), 1109 – X ZR 75/08
“*Reifenabdichtmittel*”

Under German law, in a claim in two-part format, it does not matter whether a particular term is located in the preamble or in the characterising portion.

BGH, GRUR (2011), 129 – Xa ZR 149/07
“*Fentanyl-TTS*”

For “medical indication” inventions prior to the EPC 2000 revision, the EPO required the Swiss-type claim format (“use of compound X for the manufacture of a medicament for the treatment of B”). In German law, the scope of such Swiss-type claims is mostly seen as identical to that of German-type use claims (“use of compound X for the treatment of B”), the claim in each case covering both the obvious preparation or “arrangement” of a medicament for the protected indication (for example by adding to a package of pills an information leaflet giving the protected indication), and the sale of a medicament which has obviously been prepared for the protected indication. It has not yet been decided whether the actual use of a medicament, e.g. by a doctor treating a patient, can infringe a Swiss-type claim, but due to the clear wording of such claims (“for the manufacture of a medicament”) it appears doubtful that use by a doctor would constitute infringement. The general assumption in German case law is, however, that doctors are not exempted *per se* from infringement.

Swiss-type claims

OLG München (Munich Higher Regional Court), Mitt. (1996), 312 – 6 U 3108/95;
LG Hamburg (District Court) Mitt. (1996), 315 – 315 O 224/95

Numerical figures and dimensions given in patent claims are usually assumed to be precise, thereby excluding differing embodiments. Yet they are also basically open to construction, for example to allow for normal manufacturing tolerances or for protection under the doctrine of equivalence (see below).

Numerical figures and dimensions
BGH, GRUR (2002), 511 – X ZR 43/01
“Kunststoffrohrteil”

Guidance as to how to construe claims can also be taken from the dependent sub-claims. Since sub-claims are directed to specific variants of the respective main claim, the main claim will have to be construed so as to cover these specific variants. But because of its more general nature, the main claim will preferably cover further variants, too. Where a sub-claim refers to several previous claims (for example, where claim 4 refers to “a device in accordance with claims 1 to 3”), it will depend on the circumstances (including the description and drawings) whether the sub-claim requires each and every feature of all the cited claims to be realised. It is also possible that the sub-claim may require only that the features of one or more of the cited claims be realised (in the above example, for instance, claim 4 may well require the realisation of all the features of claim 1, but not the additional features of claims 2 or 3).

Relevance of sub-claims

BGH, GRUR (2014), 650 – X ZR 31/11
“Reifendemontiermaschine”

The protection conferred by a product patent usually extends to every embodiment which realises all the features of the claim. The purpose for which the embodiment may be intended or used is usually irrelevant for a finding of infringement of a product patent.

Types of patent claims

The protection conferred by use patents extends to the claimed use, and usually also to every embodiment which is obviously prepared or “arranged” for the protected use. Depending on the circumstances, such obvious arrangement may be inferred from the product design, a product manual or package leaflet with which the embodiment is sold.

BGH, GRUR (1990), 505 – X ZR 29/88
“Geschlitzte Abdeckfolie”

The protection conferred by process patents extends to carrying out the actual process and, under **Section 9, sentence 2, number 3 PatG**, also to every product which the protected process directly yields. Whether a process patent protects a certain sequence of the claimed process steps only (the sequence as in the wording of the claim), or other practical sequences too, depends on the circumstances.

BGH – X ZR 105/06

Supplementary protection is awarded in each of the above categories by the rules of contributory infringement under **Section 10 PatG**, which are not discussed here.

The priority date of the patent is relevant to any construction of the claims, but knowledge which may influence the construction of certain claim terms but which did not become accessible to the person skilled in the art until after the priority date is not.

Relevance of priority date
BGH, (2002) 33 IIC 873 – X ZR 168/00
“Schneidmesser I”

The scope of protection can extend beyond the explicit disclosure of a patent. This means that it is possible for embodiments to be protected but not directly disclosed. This is a consequence of the fact that a patent needs to disclose only one of several ways to carry out an invention, and also of the fact that equivalents of the explicitly disclosed teaching are protected under German law (see below). A common example of protection going beyond the explicit disclosure is a claim directed to a group of chemical substances by way of a Markush formula with several variables. However, by way of exception, the BGH held that a patent may be invalid under **Article 138(1)(b) EPC** due to lack of enabling disclosure if the claims are overly generalised and exceed the inventive contribution to the art.

Scope of protection can go beyond explicit disclosure

BGH, GRUR (2010), 414 – Xa ZR 100/05
“*Thermoplastische Zusammensetzung*”

Claim construction cannot be governed by the prior art. So the mere existence of the prior art has no influence on the way a claim is construed. However, the description of the invention is relevant if it discusses the prior art. It may be that the description refers to a certain piece of prior art as a standard solution and adopts one or more technical features of this prior art for the claimed invention. If this is the case, then the construction of the respective terms may be influenced by the technical features of this adopted prior art. But it may also be that a patent refers to a certain piece of the prior art only as background, with which the invention is contrasted, without adopting any of the prior art features for the claimed invention.

The prior art itself is irrelevant to claim construction, but the description of the invention is relevant if it discusses the prior art

When construing claims, no account may be taken of the personal intentions of the inventor. Hence, it makes no sense to let the inventor testify as to what he wanted to achieve with his invention. In order to ensure legal certainty for third parties, claim construction must be governed by objective criteria. The BGH has said that the actual aims of the inventor do not matter, but that the technical effect achieved by the invention does. The problem solved by an invention must be inferred from what the claimed teaching objectively achieves.

Claim construction is objective; the personal intentions of the inventor do not matter

BGH, GRUR (2010), 602 – Xa ZR 36/08
“*Gelenkanordnung*”

Insofar as certain aims are expressed in the description, such aims can be relevant for claim construction. Any aims stated in the description can help in identifying the problem which is objectively addressed by the invention. Furthermore, if the description discusses certain disadvantages of the prior art and says that these disadvantages are remedied by the invention, this can influence the claim construction. Preferably, the claims should be construed in such a way that the criticised aspects are indeed remedied.

BGH, GRUR (2012), 803 – X ZR 98/09
“*Calcipotriol-Monohydrat*”

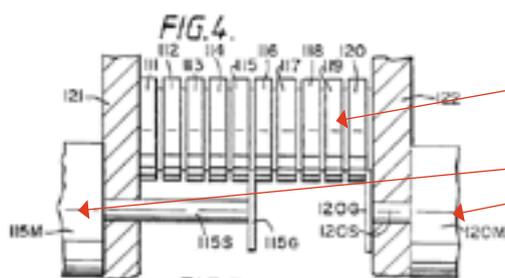
An example from German case law may help illustrate the interplay between the purposive construction of claims, the description of the prior art and the objective achievement of the claimed teaching. EP 2 032 364 B1 claims a numbering device for carrying out typographic numbering in sheet-fed or web-fed numbering presses. Claim 1 reads:

Example from case law on purposive construction of claims
 OLG Düsseldorf – I-2 U 85/12;
 Düsseldorf LG – 4b O 97/12;
 Mannheim LG – 7 O 162/12; all these decisions assumed non-infringement, in preliminary injunction proceedings and in an action on the merits respectively

1. A numbering device (1) for carrying out numbering in sheet-fed or web-fed numbering presses, said numbering device (1) comprising a numbering unit (6) with rotatable numbering wheels (7) carrying alpha-numerical symbols thereon, which numbering wheels (7) are disposed next to each other and rotate about a common rotation axis, said numbering device further comprising electro-mechanical actuation means for setting the position of said numbering wheels (7),
 said electro-mechanical actuation means comprising a plurality of independent driving means (15, 18-23; 23*) for actuating a corresponding plurality of said numbering wheels (7),
 and wherein each independent driving means (15, 18-23; 23*) at least comprises an electric motor (15) driving the associated numbering wheel through a gearing (16, 19-23; 23*), characterized in that said electro-mechanical actuation means are entirely located within said numbering device (1) and are mechanically autonomous.

As the person skilled in the art of developing devices for sheet-fed or web-fed printing knows, it is advantageous for a numbering device to have a small size, since the prints which are to be numbered may have a small size and are usually located in rows and columns, each directly adjacent to the next. However, claim 1 does not explicitly refer to a particular size or to particular dimensions of the numbering device. It only requires the actuation means (motors and gearing) to be “entirely located within” the numbering device. This could be construed in two ways. Firstly, the expression “entirely located within” could simply require the actuation means to be surrounded by a casing, regardless of the size and dimensions of the casing and the overall device. Alternatively, “entirely located within” could require a certain allocation of actuation means in relation to other necessary elements of a numbering device, thereby indirectly addressing the size of the overall device.

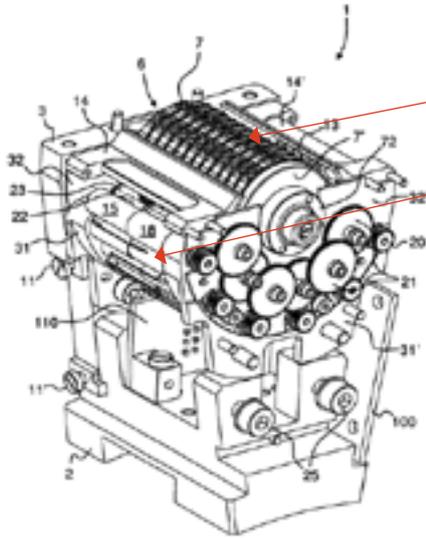
The German courts thought that the second alternative was correct. Their opinion was based firstly on the discussion of the prior art in [0018] of the description of the patent in suit. There the prior art according to US 4,843,959 is described as disadvantageous, because the actuation means are located on both sides of the numbering wheels, thereby “preventing side-by-side use of multiple numbering devices or at least greatly restricting the ability to dispose multiple numbering devices one next to the other in a compact manner”.



Prior art
 Numbering wheels

Prior art
 Actuation means (protruding on the sides of the numbering wheels, making the device larger in size)

Secondly, it was based on the preferred example of the patent in suit, where no actuation means protruded further along the axis of the numbering wheels than the numbering wheels themselves, including their support.



Preferred example
Numbering wheels

Preferred example
Actuation means (not protruding on the sides of the numbering wheels)

The courts assumed that, based on a purposive claim construction, the actuation means would not be “entirely located within” a numbering device as required by claim 1 if they protruded further along the axis of the numbering wheels than the numbering wheels themselves, including their support. Such a narrow scope was required because the claimed embodiments would otherwise have the same disadvantage as the prior art criticised at [0018] of the patent in suit.

Accordingly, the following contested embodiment was found not to infringe, because actuation means partly protruded further along the axis of the numbering wheels than the numbering wheels themselves, including their support, thereby increasing the overall size of the device.



Contested embodiment
Numbering wheels

Contested embodiment
Actuation means (partly protruding on the sides of the numbering wheels)

Turning once again to general German case law, it is accepted that where a patent claim specifies a certain effect, purpose or function, such specification can have different implications. Depending on the circumstances, it may mean that the claimed embodiment not only has to comply with any spatial or physical definition contained in the claim language, but must also be suitable for achieving the relevant effect. Such specification of an effect can indirectly require certain spatial or other properties of the claimed teaching that do not result from other claim terms.

It is important to note that it is usually sufficient for the user to be *enabled* to achieve the relevant effect. Where an embodiment can be used in several ways, it does not matter whether the user actually achieves the relevant effect, or whether a product manual even discourages him from achieving the relevant effect, as long as he could achieve this effect. It is also possible for the spatial and physical terms of a claim to be sufficient to achieve the intended effect, in which case any additional specification of a certain effect in the claim language may be irrelevant. In this context, the BGH has stated that specifications of a certain effect, purpose or function usually do not limit the scope of protection of a product claim.

The German position is that there is generally no “file wrapper estoppel”. Since neither **Article 69 EPC** nor **Section 14 PatG** refers to the prosecution history, it may not be taken into consideration when construing patent claims.

The BGH recently held that the question of whether or not patent publications such as the officially published patent application or earlier versions of the patent (which have been amended for instance in opposition proceedings) might be relevant when it comes to construing the claims is still open. Differences between the content of earlier publications and the final patent might help in construing the claims of the final patent.

It is accepted that comments made by the applicant during prosecution regarding the understanding of certain terms can be of significance (but have no binding effect) for assessing the level of understanding of the person skilled in the art.

Where decisions in invalidity proceedings exist, the reasoning in these decisions may also be of significance regarding the way in which certain terms are understood by the person skilled in the art. Invalidity proceedings will have a binding effect on claim construction if the outcome of the proceedings was an amendment of the claims. The reasoning regarding the differences between the original and the amended version is as relevant to the construction of the amended claim version as any patent description.

Effects, purposes or functions specified in claims

BGH, GRUR (2009), 837 – Xa ZR 140/05 “Bauschalungsstütze”; GRUR (2006), 399 – X ZR 14/02 “Rangierkatze”; GRUR (2006), 923 – X ZR 105/04 “Luftabscheider für Milchsammelanlage”

BGH, GRUR (1991), 436 – X ZR 121/88 “Befestigungsvorrichtung II”

No file wrapper estoppel

BGH, (2011) 42 IIC 851 – X ZR 16/09 “Okklusionsvorrichtung”; X ZR 117/11 “Polymerschaum”

BGH, (1997), 3377 – X ZR 73/95 “Weichvorrichtung II”

Decisions in invalidity proceedings

BGH, GRUR (1998), 895 – X ZR 57/96 “Regenbecken”; GRUR (1979), 308 – X ZR 63/75 “Auspuffkanal für Schaltgase”

Although the construction of patent claims is performed from the perspective of the notional addressee, or person skilled in the art, it is a question of law for the court, not expert evidence. Evidence as to the meaning of technical terms may only be given within the context of the claims and specification.

Claim construction is a question of law
BGH, GRUR (2007), 410 – X ZR 74/05
“Kettenradanordnung I”

The scope of protection of a given patent must always be the same, irrespective of the context in which the patent is examined. In other words, the same rules for claim construction apply for infringement as they do for invalidity, which means that the scope of protection must be construed without regard to any allegedly infringing embodiment.

Same rules for claim construction apply for infringement and for invalidity issues
BGH, GRUR (2009), 837 – Xa ZR 140/05
“Bauschalungsstütze”

The basic rule that the scope of protection must be the same in both infringement and invalidity proceedings requires special attention in bifurcated systems such as Germany’s, where infringement and invalidity are tried before different courts. Under a bifurcated system patentees may be tempted to advocate contradicting claim constructions. This is the so-called “Angora cat” problem. When validity is challenged, the patentee says his patent is very small (and therefore hard to challenge with prior art). The analogy here is that of a cuddly cat with its fur wet or smoothed down. When the patentee goes on the attack, the cat’s fur bristles, and it doubles in size (making the patent hard for third parties or alleged infringers to circumvent). German law provides for the following safeguarding measures to “tame” the Angora cat:

Solving the “Angora cat” problem in a bifurcated system

- Based on the presumption of good faith, any limitation on the scope of protection also applies in infringement proceedings if the patentee has defended the validity of the patent in invalidity proceedings by declaring such limitation, and if the alleged infringer was party to these invalidity proceedings.
- Any party is free to cite the pleading regarding claim construction which the other party may have submitted before another court in the past. Any inconsistency between the submissions made by a party regarding claim construction can be considered by the court.
- The BGH is the final instance in Germany in both infringement and invalidity cases, where claim construction in the context of infringement and invalidity issues is “under one roof”.

BGH, GRUR (1993), 886 – X ZR 6/91
“Weichvorrichtung I”; BGH (1997), 3377 – X ZR 73/95 “Weichvorrichtung II”

Under German law it is not admissible to dismiss an infringement action simply because the claims are found to be ambiguous. However, it is regarded as the responsibility of the patentee to clearly state in the patent claims what he seeks protection for. If ambiguities remain that cannot be resolved, the court is free to adopt a claim construction that is not in the patentee’s favour (in other words, to adopt a narrow construction of the claims, preserving the best possible freedom to operate for third parties).

Unclear patent claims
BGH, GRUR (2002), 511 – X ZR 43/01
“Kunststoffrohrteil”; BGH, GRUR (2009), 653 – X ZR 95/05 “Straßenbaumaschine”

Where a European patent is involved, German courts will consider decisions rendered by the EPO or by other national courts in parallel litigation relating to the same patent. The same applies to questions of law such as claim construction. Deviations from EPO or non-German decisions are reasoned.

Consideration of EPO decisions and parallel litigation in other European countries
BGH, GRUR (2010), 950 – Xa ZB 10/09
“Walzenformgebungsmaschine”; BGH,
(2014), X ZB 1/13 “Sitzplatznummerierungs-
einrichtung”

Literal infringement

A literal infringement is assumed if each and every claim feature is realised in a way that is identical to the – properly construed – meaning of the claim features.

It does not matter whether the teaching of the claim features is realised systematically or coincidentally.

As long as each and every claim feature is realised, infringement will not be excluded if certain features are added, or the desired technical effect is improved or made worse. Consequently, infringement is not excluded even if an addition to the contested embodiment is protected by a (more recent) patent.

Addition, improvement, worsening

The doctrine of equivalents

According to the German position, the scope of protection of a patent extends beyond literal infringement. Products/uses/processes will not be protected if they do not realise one or more claim features and if the technical function of the missing features is not fulfilled by other features. No claim feature may be treated as irrelevant. But under certain conditions, products/uses/processes can be protected even if one or more claim features are realised in a way which is modified but nevertheless still similar to the teaching of the patent claims. Such supplemental protection of “equivalents” is regarded as integral to the concept of providing the patentee with fair protection.

Infringements under the doctrine of equivalents are assessed using the following three-step test, which the BGH adopted in its “*Schneidmesser I*” judgment:

Three “*Schneidmesser*” questions
BGH, (2002) 33 IIC 873 – X ZR 168/00
“*Schneidmesser I*”; see also BGH judge
Meier-Beck, (2005) 36 IIC 339

- First, does the contested product/use/process solve the technical problem addressed by the claimed invention by means which are modified vis-à-vis those of the claimed invention (otherwise there would be literal infringement), yet have the same technical effect?
- If so, would the person skilled in the art, based on their general knowledge and skills (that is, without inventive efforts), have been able to identify the means of the contested product/use/process as having the same technical effect?

- If so, are these considerations by the person skilled in the art geared toward the meaning of the patent claim in such a way that the person skilled in the art would consider the contested product/use/process as a technical solution equal to a literally infringing product/use/process?

If all three questions are answered in the affirmative, there is infringement under the doctrine of equivalents.

With respect to the third question, it used to be regarded as an argument in favour of an equivalent infringement if the modified features of a contested embodiment were mentioned in the description. But in two recent judgments, the BGH has held that the opposite is true. If the description discloses a number of ways in which a specific technical effect can be achieved, but only one of these ways is included in the patent claims, the use of one of the other (described) ways will not, as a rule, constitute an infringement under the doctrine of equivalents. The patentee is then assumed to have made a decision against claiming protection for variants which he knew (because he explicitly referred to them in the description), but which he did not explicitly claim. However, an infringement under the doctrine of equivalents is still possible if the specific effect of the modified features corresponds to the effect of the explicitly claimed features, and if the specific effect of the modified features differs just like the effect of the claimed features from those variants which are only described, but not contained, in the claims.

BGH, (2011) 42 IIC 851 – X ZR 16/09 “Okklusionsvorrichtung”; GRUR (2012), 45 – X ZR 69/10 “Diglycidverbindung”

These somewhat intricate rules have been applied by the lower-instance courts. If, for example, a patent explicitly claims one particular salt of an active pharmaceutical ingredient (e.g. pemetrexed dicalium), but does not describe or claim any other salt, then it also covers as an equivalent the obvious variant of another well-known salt which has the same specific effect (e.g. pemetrexed disodium).

Düsseldorf LG – 4b O 114/12

Even under the bifurcated German system, a specific invalidity defence exists against infringements under the doctrine of equivalents (but not against literal infringements). The contested product/use/process is exempted from infringement if the combination of its features was obvious from the prior art relevant for the patent in suit, so that a patent expressly claiming the invention with the modified means would not have been granted.

“Formstein” defence against equivalent infringement
BGH, GRUR (1986), 803 – X ZR 28/85
“Formstein”; GRUR (1999), 914 – X ZR 22/97
“Kontaktfederblock”