Patent litigation A-Z: Block 1

Patents: Procedures to obtain a patent and legal framework
Block 1
Patents: Procedures to obtain a patent and legal framework

The first block of the “Patent litigation A-Z” material relates to the definition and understanding of patents as objects of litigation.
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A basic definition

A patent is a grant by the state of an exclusivity right to work an invention. The invention is usually a **product** or a **process**.

The patent is limited in time.

Like other forms of intellectual property, the rights provided by a patent do not permit their owner to do anything; they are rights to stop other people doing things and are essentially negative: they enable the patent holder to exclude others from practising the invention within the state which granted them.

General considerations

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

Patents are currently *domestic in nature* – there are at present no transnational patents. 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 presently 38 states within the EPC, each having domestic patent legislation which in its essentials follows corresponding provisions of the EPC.

**Patentability**

In order to gain patent protection, five fundamental elements must be satisfied by an invention:

(1) there must in fact be an invention;
(2) the invention must be new;
(3) it must possess "inventive height" over what has gone before (i.e. involve what is called 'an inventive step');
(4) it must be susceptible of industrial application, and;
(5) it must not fall within a list of 'excluded' subject-matter

These fundamental requirements are found in **Art. 52 of the 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. Reaching the 20-year term is contingent upon the payment of periodic renewal fees. Failure to pay the renewal fees may cause the patent or the patent application to 'lapse'.

**Introducing infringement**

A patent provides its owner with 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 noted above, at present there are no transnational patents: if an individual or company wishes their invention to be protected in different states, they must ensure that they hold rights in each state in which protection is desired. It is not, for example, infringement of a German patent to produce the invention in France (for example), or to sell allegedly infringing products there – although it would be an infringement to import infringing products made in France into Germany.

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.
Basic economic considerations

Fundamentally a patent is concerned with information – instructions for how to make, perform or operate a product or process. Information is essentially a free good – i.e. it 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 – i.e. it is not (barring some sort of legal intervention) exclusive once disclosed. This causes problems.

In the absence of some sort of protection, once an invention has been created it is freely appropriable if disclosed and therefore of strictly limited worth to its creator. It is, of course, worth an amount commensurate with the market value of the invention. However, if costlessly copied, this value is simply equal to the production cost, as competition will push the price down.

By providing an exclusive right over the invention, the patent provides a way of dealing with the problems of the free and public nature of information. However, as noted above, such exclusive rights are not always seen as beneficial. Like other forms of intellectual property, while in force, patents stop people doing things. The patent may therefore need some justification.
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 to 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 to take the invention to the patent office that 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 justifications 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, and 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 that 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 the patent 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 that 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 that enable a certificate (a Supplementary Protection Certificate (SPC)) to be obtained which extends protection for these products for up to five years from normal 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.”


Special provisions:

The patent system as we know it today is a relatively modern innovation. The idea of a patent office with a corps of examiners to ensure that applications complied 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 for novelty, etc., only came about with the Patents Act of 1902.

Nevertheless, 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 its luxury, 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.

Other ad hoc examples of the use of monopoly to reward artisans appear throughout the middle ages in Europe and beyond.

Notwithstanding the Sybarites’ pioneering approach to the improvement of cuisine, 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

“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”.

The Statute of Venice of 1474 in all respects demonstrates a modern approach to the protection of invention. The preamble to the Statute declared the act’s intent: 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 to induce innovation – a principle that underpins the patent laws of all major states today.

The Statute contained all the essential features of a modern patent law. It provided that the devices must be novel (new and ingenious, not previously made in the Commonwealth) and reduced to perfection. It gave a term of protection (10 years), provided for the licensing of the invention, and set out a procedure for determining infringement, providing 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/reward for inventive effort is undeniable. By the mid-1500s the practice had found firm footing in England.

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 to the rest of Europe. The early years of her reign are marked by conscious acceleration of a policy to stimulate domestic industry in order that the technologically backward state might become self-sufficient. Central to this was 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.

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
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, its Section 6 made an exception for patents relating to a new manner of manufacture for a limited term. Section 6 of the Statute of Monopolies formed the foundation for English patent law 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 its own hands 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 also made the inclusion of patent claims a statutory requirement.

The mid-to-late 19th century was a time of great uncertainty for patents. 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) in support of their claim, arguing that this was clear evidence that the patent system was not needed to encourage innovation. Others made more fundamental comments, questioning the very origin of invention: “to scheme and invent [is] almost a madness with some people”.

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 nineteenth century, patents were becoming an international concern. Inter-state trade was on the increase and it was no longer possible to consider patents (or indeed any other industrial property, e.g. designs or 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 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, at which provisions that it was hoped would overcome the worst difficulties facing patentees with international interests, and would at the same time be politically practical, were debated. The resultant text of the Convention provided for new concepts like ‘national treatment’ and

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**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 Art. 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. See Art 4 of the Convention.
‘Conventional priority’ that still play a major part in patent law today.

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 states. 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 creates a procedural mechanism assisting the prospective patentee who wishes to obtain protection in more than one state. It provides a mechanism whereby 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.

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), in Munich. 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 states that are members of the European Patent Organisation, and a further two extension states.

The EPC (and also the EPO) does not concern itself with issues of enforcement and infringement of patents:

Preliminary examination: i.e. an examination to check that the application is in order. This is not an examination of the patentability of the invention in question.

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.

Extension states: i.e. states recognising European Patents upon request:
- Bosnia and Herzegovina, and Montenegro
these are purely national concerns.

Patents granted under the EPC are referred to as “European patents” but are not unitary in character. Once granted, the 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, and 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 Art. 25 of the 1989
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 down certain minimum standards for many forms of IP right.

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 requires (under Art. 27) that patents “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”. It will be noted that Art. 52 EPC mirrors this provision closely.
Introduction

The term of protection of a patent is 20 years from the date of filing the application. However, the period of effective patent protection is significantly reduced in the life sciences industry, as compared with 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 (like pesticides or insecticides) can be placed on the market.

Satisfying these regulatory requirements for a new medicinal product typically requires the conduct of pre-clinical studies and clinical trials to demonstrate the safety, efficacy and quality of the product, which takes many years (around 12 on average). It was recognised that the effect of these mandatory requirements would therefore reduce the period of exclusive exploitation under a patent to only eight years, placing the European life sciences industry at a significant disadvantage as compared with the US and Japan (where pharmaceutical patent term extensions have been available since the 1980s). Therefore 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.

Art. 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: [...]
Legal framework – SPCs

1. 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 may affect the functioning of the internal market. Accordingly, 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.

2. Plant protection products – SPC Regulation

Regulation (EC) No 1610/96 creating an SPC for plant protection products entered into force on 8 February 1997 (Plant SPC Regulation). 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:

“(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.”

3. 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 national patent offices, national courts and the Court of Justice of the European Union (CJEU) as a guide to the
interpolation of the SPC Regulations.

SECTION A: Medicinal SPC Regulation

Key definitions

Certificates

SPCs (or ‘certificates’, as they are referred to in the legislation) are the mechanism by which the innovative 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 patent expiry 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’ (which is 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(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(b) – Product**

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

The CJEU recently confirmed its approach in Case C-210/13 GlaxoSmithKline Biologicals v Comptroller-General of Patents (GSK). The case concerned two SPC applications relating to an ‘adjuvant’ which is used in combination with a particular influenza vaccine. The case turned on whether the adjuvant is an ‘active ingredient’ and therefore capable of satisfying the ‘product’ definition in the Medicinal SPC Regulation. With reference to its earlier judgment in Case C-431/04 Massachusetts Institute of Technology (MIT) and to the Explanatory Memorandum, the CJEU confirmed that ‘product’ is to be understood to mean 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’.”.

In Case 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.

Questions have recently been referred to the CJEU in Case C-631/13 Forsgren v Österreichisches Patentamt to ascertain whether a SPC may be granted for an active ingredient (Protein D) that is covalently bonded to other active ingredients in the medicinal product, but functions in humans or in animals.

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

See *MIT* at §§19, 21, 25-28; *GSK* at §§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.

Also see the recent reference in *Forsgren*, described below.

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

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

See also the *Bayer case* concerning the meaning of
nonetheless retains its own therapeutic effect. Related questions have also been referred on Article 3(a) and (b) and the nature of the marketing authorisation for the medicinal product. The CJEU’s decision remains pending.

**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 which designates the Member State in which the SPC application is lodged.

**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 the Member State 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.

**Overview of the SPC application process**

Generally speaking, an SPC application is to 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 SPC Regulations).

Under Article 7 SPC Regulations, 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 is submitted; or

(b) the date on which the basic patent is granted (if later).

Article 19 Regulation (EEC) No 1768/92 (now repealed) previously provided 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 Case 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.

Legal requirements

**Article 2 – Scope of the Regulation**

According to Article 2 Medicinal SPC Regulation (and subject to 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 Case C-195/09 *Synthon v Merz Pharma* (confirmed in Case C-427/09 *Generics v Synaptech*) 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 3 – Conditions for obtaining a certificate

According to Article 3 Medicinal SPC Regulation, a SPC is to be granted if, in the Member State in which an 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. Secondly, 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 a preliminary ruling on questions of interpretation of the SPC Regulation.

In Case 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:

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 Case 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.

In the context of other combination cases (Case 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 Case 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 recently held that the CJEU’s decision requires the application of the relevant rules (i.e. Article 69 EPC or s.125 UK 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, satisfies Article 3(a).

**Article 3(b)**

As reflected under Article 2 above, Article 3(b) requires that a valid authorisation has 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 Case C-422/10 *Georgetown University v Comptroller General of Patents* (*Georgetown I*).

**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).
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 only A, 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, 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 products 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 Case C-484/12 Georgetown University v Octrooicentrum Nederland (*Georgetown II*) and Case 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 §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 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.

**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 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*. 

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 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.
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 Case C-130/11 Neurim Pharmaceuticals v Comptroller-General of Patents (Neurim). In this case, Neurim 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.

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 (see above) and AstraZeneca (see below)). However, the CJEU’s reasoning in §§25 and 26 of Neurim nonetheless
suggests that it should be irrelevant whether the earlier use is veterinary or human and whether or not 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 the meaning of 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.

**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 provides 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 Case 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 etc.

**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, and 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 an SPC in circumstances where the patentee and the marketing authorisation holder are not the same entity.

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*”.

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

When calculating the duration of a SPC, the Regulation

* Hereafter, the masculine shall include the feminine.
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:

\[
(A - B) - 5 \text{ yrs} = \text{SPC duration}
\]

A = First marketing authorisation in the EU/EEA  
B = Filing date of the basic patent application

**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.

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

**Compliance with Directive 2001/82 or 2001/83**

The CJEU held in Case C-127/00 Hässle v Ratiopharm (Hässle) 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.

Importantly, 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).

Secondly, the CJEU 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.

These principles were recently confirmed in November 2013 in Case 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 as the first authorisation to place the product on the market in the EEA under Article 13(1).

Veterinary or human marketing authorisations

In Case 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, i.e. 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).

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 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 Case 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 the SPC itself, an application for a paediatric extension is to be lodged with the competent intellectual property office of the Member State concerned.

Under Article 7(3) and (4), an application 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, an application for a paediatric extension must now be made not later than two years before the SPC expires.

**SECTION B: Plant SPC Regulation**

The main principles and objectives of the Plant SPC Regulation are the same as those underlying the Medicinal SPC Regulation, i.e. 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, ‘active substances’ is defined to some extent under Article 1.3.

The CJEU very recently considered the meaning of ‘active substances’ as applied to ‘safeners’ in Case 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 Case 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 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 later ruled in Case 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, the CJEU distinguished **Hogan Lovells** on the basis that ‘emergency’ authorisations under Article 8(4) Directive 91/414/EEC are only granted in cases where there is an immediate threat to public health and the absence of a MA would result in irreparable harm.

**Article 1 Plant SPC Regulation**

3. ‘**active substances**’ - substances or micro-organisms including viruses, having general or specific action:
   - (a) against harmful organisms;
   - (b) on plants, parts of plants or plant products;
   - (c) protecting plants from other plants.

**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 authorization procedure as laid down in Article 4 of Directive 91/414/EEC (6), or pursuant to an equivalent provision of national law.
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 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.

National law if it is a plant protection product in respect of which the application for authorization 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 authorization 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.
The European Patent Office and the Administrative Council

The European Patent Office (EPO) is the executive arm of the European Patent Organisation, an intergovernmental organisation set up in 1977 on the basis of the European Patent Convention.

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 contracting member states. There are additional 2 “extension states” recognising European patents upon request.

The European Patent Organisation has two organs: the European Patent Office and the Administrative Council. The latter is responsible for supervising the former’s activities.(Art. 4 EPC)

The EPO’s languages

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

Applications may be filed at the EPO in any language. However, according to Art. 14(2) EPC, applications


(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.
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.

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.

Composition of the EPO

The European Patent Office is made up of the following departments which are entrusted with procedures under the EPC:

- the Receiving Section
- search divisions
- examining divisions
- opposition divisions
- the Legal Division
- boards of appeal
- the Enlarged Board of Appeal

The Receiving Section is responsible for the preliminary examination of applications for patents – i.e. making sure the application is complete and the relevant fees have been paid (Art. 16 EPC).

Search divisions are responsible for drawing up search reports – i.e. creating a list of the prior art or other documents which may be considered when deciding whether the invention to which a patent application relates is patentable (Art. 17 EPC).

Examining divisions are responsible for substantive examination of patent applications – i.e. examining them to determine whether the claimed invention is patentable (Art. 18 EPC).

Opposition divisions are responsible for examination of
any oppositions against European patents. Oppositions are objections raised by third parties to the grant of a European patent. There is a nine-month window following the grant of European patent in which notice of opposition may be filed. Successful opposition will cause the patent to be invalidated at source. If the opposition period has passed and the European patent has entered the national phase, someone wishing to invalidate the patent will have to bring separate revocation actions in all states in which the patent has effect (Art. 19 EPC).

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

**Boards of appeal**

There are currently 27 technical boards of appeal, hearing appeals from decisions of the Receiving Section and the examining and opposition divisions, and one Legal Board of Appeal, hearing appeals from decisions of the Legal Division. There is also a Disciplinary Board of Appeal for dealing with conduct-related appeals.

The boards of appeal are independent of the EPO and are bound only by the EPC itself.

Decisions of the boards are made available via the European Patent Register and the EPO's Official Journal; databases of decisions are also available online and on DVD.

**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 directly 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 (or any body equivalent thereto) may file a patent application (Art. 58 EPC).

An application may be filed by single or multiple applicants, and by different applicants either jointly or with each designating different contracting states (Art. 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 (Art. 60 EPC).

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

**Designation**

An applicant for a European patent “designates” the contracting member states in which protection is desired.

By default, when filing a European patent application all the contracting states for which the EPC has already entered into force on the date of filing are deemed to be designated.

However, the designations must subsequently be confirmed by payment of the appropriate fee. Accordingly, before payment of this fee, applications may be withdrawn in states where protection is not required.
Application process in outline

<table>
<thead>
<tr>
<th>Filing date</th>
<th>Publication date</th>
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<tr>
<td>Application made</td>
<td>Preliminary &amp; formal Examination</td>
<td>Search report issued</td>
<td>Substantive examination</td>
</tr>
</tbody>
</table>

18 months

Significant dates and periods

The patent system has a number of critically important dates or periods of time that have special significance within the system: the priority date; the filing date; the date of publication; the date of grant; and (for a European patent only) the opposition period.

The date of filing and priority

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

The filing date is the date from which the term of the patent is calculated (Art. 63 EPC).

The filing date will also, in the absence of any other information, be taken to be the priority date of the application – i.e. the date at which the invention’s patentability is assessed (novelty, inventive step, etc.).

Matter made available to the public before the invention’s priority date will be considered prior art.

Claiming earlier priority

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

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.
In order to sustain a claim for priority, the application must be supported by matter disclosed in the earlier application – in practice this means the specific combination of features present in the claim must at least implicitly be disclosed in the previous application (decision G 2/98 of the Enlarged Board of Appeal).

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.

It is not necessary for the applicant to provide any claims in order to obtain a date of filing. If the application is filed without claims, but satisfies all 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 also examines it to ensure that it meets a number of formal requirements. These are laid down in Art. 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.

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;
The Receiving Section also, inter alia, checks the claims and description in order to ensure that the title of the invention is in general accord with Rule 42 EPC and ensures 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.

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

The search will be made on the basis of the claims, with due regard to the description and drawings (if any) (Art. 92 EPC).

A search report is prepared containing the results of the search, in particular identifying the documents constituting the relevant prior art. In addition, a non-binding opinion on patentability is issued.

Publication
The application is 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. The application may, however, be published before this if requested by the applicant and provided the relevant fees have been paid (Art. 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), and specify, where possible, the person(s) designated as the inventor(s).

Following publication

Provisional protection in all states designated may be obtained upon publication. Applicants may therefore claim reasonable compensation from those that infringe their patent applications after this point – provided that the application eventually proceeds to grant. This is notwithstanding that 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 (and also an extension fee (if applicable)).

After publication of an application, third parties may present observations on the patentability of the invention to which the application or patent relates, as long as proceedings are pending before the EPO.

Substantive examination

Following a request for examination and the payment of an 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.

During substantive examination, the patentability of the application is considered – i.e. whether the invention, inter alia, is new, involves an inventive step, is capable of industrial application, and does not fall within
excluded subject-matter.

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 invite the applicant, as often as necessary, to file his observations and, subject to Art. 123(1) EPC, to amend the application so as to render it compliant.

Pre-grant amendment

An applicant may amend their application before the patent has been 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 Art. 123(1) EPC the applicant 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 Art. 94(3) EPC).

The applicant 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 (Art. 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 (Art. 84 EPC); and

(iii) they must comply with Rule 137(5) EPC in that 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.

Hereafter, the masculine shall include the feminine.
Grant

Once 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 in 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 not unitary; it 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 a translation of the specification or at least of the claims into an official language of the state concerned with the national patent office. 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 – these will usually be the applicant’s competitors (although they need not be) – if they believe that it should not have been granted (for example, because the invention lacks novelty or does not involve an inventive step).

Notice of opposition must be filed within nine months of the patent’s grant being mentioned in the European Patent Bulletin.

The examination of oppositions is handled by an opposition division.

Renewal

The maximum life of a patent is 20 years (measured from the filing date). However, the continuing effect of the patent is subject to payment of periodic renewal fees. European patent applications are subject to renewal fees in respect of the third and each subsequent year, calculated from the date of filing (see Art. 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 are constant.

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 belated renewal fee is paid within the same period.

Art. 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 Patent Cooperation Treaty

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

Art. 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 provides the only system for filing and processing international patent applications in a single procedure before the applicant embarks on the national grant procedures.

The PCT 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 procedure.

Object of the PCT

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,

**PCT**

**PCT contracting states**

**WIPO website**
http://www.wipo.int/pct/en/

**Preliminary examination**
It is 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.

**Relation to Paris Convention**
PCT is a "special agreement" according to Article 19 of the Paris Convention:

Art. 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 of the PCT.

**Art. 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
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 search and
- the (optional) establishment of a preliminary examination report by an International Preliminary Examining Authority.

The "national phase" starts upon completion of the international phase, when the applicant decides to continue processing the application before the regional or national patent offices with the aim of obtaining regional or national protection. There are as many national phases as procedures initiated before each regional or national patent office, but the wording "national phase" is also used to refer to them as a whole.

Applying for a patent under the PCT

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

An international application has to be filed with the competent receiving Office, i.e. at the discretion of the applicant either with:

- 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, or
- 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, or
- the competent regional office, e.g. the European Patent Office (EPO), if at least one applicant is a national or resident of a contracting state to the European Patent Convention (EPC).
Art. 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.

Elements of the international application

Any international application must contain the following elements:

- PCT request (Art. 4 PCT)
- description (Art. 5 PCT)
- claim(s) (Art. 6 PCT)
- drawing(s) (where required) (Art. 7 PCT) and
- abstract (Art. 3(3) PCT).

PCT request

The request shall 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.

Art. 3 PCT: The international application
(3) 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.

Art. 4 PCT: The request
See below
Description, claims and abstract

Art. 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".

Art. 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".

Art. 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" (Art. 7(1) PCT).

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 Art. 11(1) PCT are fulfilled. These requirements are:

(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 part which on the face of it appears to be a description,
   a part which on the face of it appears to be a claim or claims.

Art. 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.

Art. 11 PCT: Filing date and effects of the international application
(1) The receiving Office shall accord as the international filing date the date of receipt of the international application, provided that that Office has found that, at the time of receipt:
   (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 part which on the face of it appears to be a description,
      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" should not be interpreted as if there was any further filing date in respect of an international application. The word "international" only refers to the fact that the application concerned was filed as an application under the PCT.

The international search

Each international application is the subject of an international search carried out by an International Searching Authority (ISA, e.g. the EPO), which establishes for each international application 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 and
- the identification of the fields searched.

The international search report shall be published by the International Bureau of WIPO (Art. 21(3) PCT).
Written opinion of the ISA

The written opinion of the International Search 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.

The supplementary international search

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.

International publication

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

### Art. 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. [...]
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.

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**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.

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**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.

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**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.

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**The international preliminary examination**

The applicant 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.

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 Art. 34 PCT are filed for the International Preliminary Examining Authority to take into account.

The national/regional phase

At the end of the international phase (at the latest), the applicant must decide whether he wants to proceed with the international application and, if so, where he wants to do so. He then enters the national/regional phase before the relevant 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 (Art. 22 PCT).

If the applicant wishes to obtain a European patent, he must enter "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 decision.

Art. 22 PCT: Copy, Translation, and Fee, to Designated Offices
See below

Art. 27(5) PCT: National requirements
See below

Art. 39 PCT: Copy, translation, and fee, to elected Offices
See below

Art. 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

Art. 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. [...] [...

Art. 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.

* Hereafter, the masculine shall include the feminine.
Art. 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; [...]
Introduction

Due to the globalisation of markets and the increase of inter-state trade, by the end of the nineteenth century there was a growing need for internationally common standards in applying 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 their patent application in one country could be deemed to be novelty-destroying prior art in another country, if the application was filed subsequently. But national specificities and translation requirements in patent application procedures made it scarcely possible for inventors to file patent applications for the same invention at the same time in more than one country. Consequently, whenever the invention was going to be marketed shortly after the first patent application, the invention was no longer patentable in some of the other intended markets.

In order to solve this problem and to safeguard the inventor’s interests, the legal institution of ‘priority rights’ was introduced to international law.

It was the Paris Convention for the Protection of Industrial Property, concluded in 1883, which first introduced a priority right 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

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 the year 1883.
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 to determine the state of the art of the subsequent applications within 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 is twelve months for patents. This period often allows the applicant to identify market opportunities for the invention, to continue the development of the product or process and to decide in which countries patent protection appears reasonable.

Hence, whenever an inventor is seeking patent protection for the same invention in more than one country, the principle of priority is very useful for him as he does not have to file the application in all relevant countries at the same time. As the first application is considered to have priority over subsequently filed applications and publications, the inventor still succeeds in being the first to file in other countries, even if there are other applications filed or relevant documents published in the meantime.

**Definition**

The priority date is the first date of filing a patent application. It is essential to determine whether any subsequent application for the same invention can still be assessed as novel or state of the art (obviousness). It further 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.

* Hereafter, the masculine shall include the feminine.
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 is legally accepted by that patent office. It is usually the date on which the documents are deposited at the patent office. It may also be later if there are formal errors or missing documents in the application.

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 having 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 - here 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 the earlier application.

2. **European Patent Convention**

The European Patent Convention (EPC) is an international treaty that defines in its Art. 87(1) 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). Literally, it states:

**Any person who has duly filed, in or for**

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

**Art. 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. [...].
(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 Art. 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 Art. 54(2) and (3) and Art. 60(2) (cf. Art. 89 EPC).

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

3. Patent Cooperation Treaty

The Patent Cooperation Treaty is an international patent law treaty. According to this 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 laid down in Art. 8(1) PCT, any such PCT application may contain a declaration claiming a priority right based on an earlier patent application.

4. Domestic priority rights

Some jurisdictions provide for a domestic priority right that allows an inventor to claim the priority of a first application when filing a subsequent application within the same jurisdiction. For example, Germany in Section 40 of its patent law provides the opportunity to claim a domestic priority.
Claiming priority

Claiming priority rights requires the fulfilment of certain conditions. For a European patent, the required conditions are laid down in Art. 87 and 88 EPC.

1. Timeline for claiming priority rights

An application claiming priority of an earlier application must be filed within a certain time period. The period of priority is 12 months. It starts to run on the application date of the earlier application.

2. Substantive requirements

(a) Earlier application
Claiming priority requires an earlier application for the same patent. 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.

Excluded are applications for which a domestic or foreign priority has already been claimed.

(b) Identity of the applicant
The right to priority can only be claimed by the applicant for the priority application, or by its successor in title.

(c) Identity of invention
Claiming a priority right further requires 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 requires that all 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 EPO's Enlarged Board of Appeal in case number 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’.

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

**Opinion of the EPO’s Enlarged Board of Appeal dated 31 May 2001, G 2/98**


(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. application, description, claims and drawings.

3. Formal requirements
The formal requirements for claiming priority are in essence as follows:

- declaration that priority is claimed;
- information about the file number of the earlier application;
- copy of the previous application;
- if necessary: 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;
• the applicant for a patent has - during the priority period of twelve months - time to evaluate its commercial potential, to continue the development of the invention and to decide in which countries subsequent patent applications for the same invention should be filed;

• the applicant can postpone spending time and money on foreign patent application procedures until he has received a first report on the patentability of the invention;

• the applicant can make his invention public without thereby generating novelty-destroying prior art in respect of any subsequent patent application within twelve months;

• the applicant can maintain the novelty of his invention for subsequent patent applications elsewhere within twelve months, even if someone else has applied to patent the same or a similar invention in the meantime.
Introduction

Since the end of the 1950s, the creation of unitary patent protection for the territory of the European Community/Union has been under discussion. Originally, 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, in spite of various attempts, the CPC has never entered into force because it neither simplified nor improved the EPC system.

In 2000, the European Commission reacted to this unsatisfactory situation by presenting a draft proposal for a Regulation on the Community Patent centred around 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 the critique of the complicated and expensive nature of the previously suggested litigation and language regime of the CPC, the Commission this time favoured the three-language regime of the EPC. In the subsequent discussions it became clear that the problems related to the language regime and the litigation system could not be settled. This caused the Council to state, at the end of 2010, that the “insurmountable obstacles to unanimity will persist for the foreseeable future”.

The way forward from 2011: enhanced cooperation

This turned out to be a major turning point for the EU patent because it prompted a group of EU member Article 20 TEU See below
states to formally address to the Commission a request for “enhanced cooperation” according to Article 20 TEU and Articles 326-334 TFEU.

Such enhanced cooperation allows those EU member states participating in it to make use of the EU’s institutions and to adopt legislation in one 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 cooperation; only Italy, Spain and Croatia do not participate in the scheme for the time being.

Acts adopted in the framework of enhanced cooperation are binding only on participating member states; therefore, the unitary patent will take effect only in the territories of the participating member states.

**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 European “patent package”**

In April 2011, the EU Commission proposed two draft regulations for implementing enhanced cooperation 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 one 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 “Agreement on a Unified Patent Court” (in short, the “UPC Agreement”) had been 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 EU member states, not only by those participating in enhanced cooperation; it was signed on 19 February 2013 by all EU member states participating in enhanced cooperation apart from Poland, and also by Italy, although the latter does not participate in the enhanced cooperation scheme for the time being. Contracting member states of 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, which must include France, Germany and the UK; although only Austria, Belgium, Denmark, France, Malta and Sweden have ratified the Agreement to date, the national ratification procedure is also progressing quickly in other states.

As Regulations (EU) No 1257/2012 and (EU) No 1260/2012 complement each other, the Council decided that they should apply from the same date; furthermore, their date of application is conditional upon the entry into force of the UPC Agreement.

**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. The registration of unitary effect thus requires there to be a European patent applied for and granted under the rules of the EPC. However, it will not be possible to attain double protection for an invention by a “classical” European patent and a unitary patent for the territory of the participating states.

The approach chosen means that the EPO’s existing search, examination and grant procedure remains entirely unaffected. Consequently, an applicant wanting unitary protection in the states participating in enhanced cooperation will first have to file a European patent.
or international application and get a patent granted by the EPO. The applicant does not have to decide whether he wants unitary effect for his European patent until such time as the 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 be attributed to the European patent only if it was granted with the same set of claims in all 25 participating states. If this is not the case, the EPO must reject the request for registration of unitary effect.

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 established a translation service which covers translations between English and 31 other languages; translations from and into French and German are also available for 27 languages.

However, the European legislator has 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 regulations, in which the required high quality of the machine translations cannot yet be ascertained. During this period and until such time as high-quality machine translations are available, a request for registration of a unitary patent must be filed together with

- an English translation of the patent specification,

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 EPC, in order to ensure that the translation costs do not fall upon the applicant.

*Hereafter, the masculine shall include the feminine.
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 European patent with unitary effect, the patent proprietor may have to provide a full translation of the patent at his own cost; more precisely, in the case of an alleged infringement, the alleged infringer can request of the patent proprietor 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; in the case of any dispute, furthermore, the competent court can request of the proprietor 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.[…]

**Effect of registering unitary effect**

A unitary patent takes effect retroactively from the date the EPO publishes the mention of the grant of the European patent in the European Patent Bulletin. Consequently, when the 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 the territorial scope of protection of unitary patents, a unitary patent will be protected on the territories of the member states which, on the day of registration of unitary effect, are participating in enhanced cooperation and have ratified the UPC.

**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
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. Therefore, third parties will have to consult the future “Register for unitary patent protection”, which will be incorporated in the European Patent Register, to find out which states a given unitary patent covers.

As for the substantive scope of unitary patent protection, Regulation 1257/2012 provides that it is to be uniform in all participating member states in which the patent has unitary effect. Consequently, unitary patents 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 one.

In spite of the uniform effect of unitary patents, they may be licensed for the whole or only part of the territories of the member states. Furthermore, the regulations provide the proprietor with the possibility to state to the EPO that he will grant licences of right to any interested party in return for appropriate consideration.

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**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.[…]

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**Unified payment of renewal fees**

Whereas the renewal fees for European patent applications are due at the EPO, those for granted 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 along the lines of a distribution key.

This key, along with the level of the renewal fees, is to be determined by the Select Committee. This committee is a sub-body of the Administrative Council of the European Patent Organisation set up for this purpose according to the EPC and composed of representatives of all contracting states, not only the 25 participating member states, and user organisations as observers.

**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; [...]"
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 set up with seats in Lisbon and Ljubljana, and a training centre for judges in Budapest.

As for the composition of the panels of the Court of First Instance, three judges of at least two different nationalities will form one panel; in the case of local and regional divisions, the three judges will be legally trained unless the panel requests of the President of the Court of First Instance the allocation of 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.

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 hear the appeal.

All panels are chaired by a legally trained judge.

**Jurisdiction of the UPC**

The UPC will have exclusive jurisdiction on 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; and,
apart from that,

- appeals against decisions taken by the EPO in carrying out its additional tasks relating to unitary patents; in this case, the UPC will act as an administrative court. Such actions will only be dealt with by the central division in first instance.

The competence of the central division is further subdivided between its seat in Paris and sections in London and Munich according to the nature of the patented invention. Thus,

- Paris will host the Court’s President’s Office and be in charge of patents relating to performing operations, transporting, textiles, paper, fixed constructions, physics and electricity;
- London will be charged with patents relating to human necessities, chemistry and metallurgy; and
- Munich with those relating to mechanical engineering, lighting, heating, weapons and blasting.

Apart from that, 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 request 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.

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 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
(b) refer the counterclaim for
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.

**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. [...] 

**Proceedings before the UPC**

The UPC will work to its own rules of procedure, which are currently being drafted by the UPC preparatory committee. However, the fundamental procedural rules are determined in the Agreement itself, such as:

- 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); and

**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 59: 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 [...].
• 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, “rehearing” may exceptionally be granted by the Court of Appeal if, after the latter’s final decision, the party requesting the rehearing can either 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 decides otherwise.

The UPC’s fees will combine fixed fees with a value-based component.

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;

or

• patent attorneys who are entitled to act as professional representatives before the EPO and who have appropriate qualifications in patent litigation. For this purpose, it has been suggested that a new European Patent Litigation Certificate should be created to prove the required qualifications.

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.[...]

European Patent Academy
Language of proceedings

Before a local or regional division of the Court of First Instance, the language of proceedings will in general 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 a 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.

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Article 49 UPC Agreement: 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:[…].

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Relationship between UPC and 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 a 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 member states to the UPC Agreement recognise those duties and their liability in case of violation of EU law by the UPC.

Remaining jurisdiction of national courts

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, such as actions related to the patent as an object of property.

In addition, the UPC Agreement provides for a transitional period of seven years after the entry into force of the Agreement, 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 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 concerning this patent has already been brought before a national court.

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**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.
Patent Litigation. Block 1. Module 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 defines neither ‘inventions’ nor ‘technology’. Legislators therefore have considerable leeway in defining what is patentable subject-matter.

Most jurisdictions have chosen to follow the principle of exclusion rather than attempting to define the terms ‘invention’ or ‘technology’. According to Article 52(2) of the 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’.

Although the TRIPS Agreement does not require patent protection to be granted for subject-matter that is not considered to be of a technical nature, most laws have traditionally defined inventions as comprising

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 (decision T 931/95 of the EPO’s boards of appeal).
'technical aspects’, solving a ‘technical problem’ or exhibiting a ‘technical effect’.

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) if, for example, a technical effect is achieved by the invention 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) as well as 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 particularly applies 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.
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 still 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.

The European patent system currently does not provide for a grace period (usually between 6 and 12 months) like the US or Japan that would allow the inventor to disclose his or her 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.

An 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, a patent examiner (or judge) must therefore put himself 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, he or she must decide whether he or she would have made the step from the prior art to the invention claimed in the patent.

Jurisprudence has developed indicators of non-obviousness, such as

- that the invention yields an unexpected technical effect,
- that it offers a technical advantage despite a teaching away in the prior art, or
- that it 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, however, is generally not as such 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 or her 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 it is also a ground for opposition under Article 100 EPC or for invalidity proceedings in
the case of a granted patent.

**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 or her consent.

This includes the following exclusive rights:

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

The precise scope of these rights is not defined in the law and, hence, it is up to national courts to determine whether 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 transport and temporary storage of goods in a country where these goods are protected 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 and
- 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 and
- 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 the invention. 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 clarifies the question by providing 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, the description and drawings being employed only for the purpose of resolving an 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.

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

Infringement is at present a matter for national courts.
Exceptions to exclusive rights

Certain acts and forms of use are however excluded from the exclusive rights conferred by a patent. 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);
- 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.
Furthermore, the effect of a patent may not extend to legitimate prior uses of its subject-matter (cf. Article 28 of the UPC Agreement). In countries where prior user rights are available, the patent holder may not enforce his or her right 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 or her own business to the same extent that he or she 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 a 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 called ‘compulsory licences’. In general, two kinds of compulsory licence may be distinguished. First, there are compulsory licences which ensure that patents themselves do not become barriers to legitimate invention and innovation, such as 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, or
• 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, 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 (cf. Article 83 of the Agreement). During a transitional period of seven years after the date of entry into force of the Agreement, an action for infringement or for 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, a proprietor of a European patent 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). The effect of an opt-out is that national courts will remain competent for actions related to such European patents.

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

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

The Directive includes procedures covering effective means of obtaining and preserving evidence (cf. 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 (cf. Sections 4 to 6). It also includes rules about those entitled to apply to the courts, the presumption of ownership (cf. Articles 4 and 5 of the Directive) and legal costs (cf. 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 Litigation. Block 1. Module Scope of protection

Essentials: Construction of claims

The common general knowledge of the art
The skilled addressee

Prologue

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:
(a) in determining the scope of the protection granted; and
(b) in 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 boundary 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, 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 to the alternative interpretative theory.

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* Hereafter, the masculine shall include the feminine.
* Validity is a substantial topic and is the subject of another module.
Summary of the requirements under the EPC

Under the EPC, the claims define the invention – Art. 84 EPC. The claims are also used to determine the patent’s scope of protection – Art. 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 – Art. 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, how exactly this is to be interpreted, and the significance or weight that is to be attached to such equivalents, are far from certain, as we shall see. In all cases, the reader of the patent is deemed to be ‘the skilled reader’ (see below).
Putting claim construction into practice – some fundamentals

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 a question for the 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 construction of the claims is performed 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: 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 domestic 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 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 “skilled addressee”**

The person skilled in the art is referred to in a number of places within the EPC. For example, *Art. 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. *Art. 83*, concerning sufficiency of disclosure, and *Art. 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, the prior art must be viewed through the eyes of the skilled addressee in considering whether an invention is new. 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.

**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 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 critical 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 it 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). Therefore 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 whole state of the art. Knowledge only becomes “common general knowledge” when it is taken up into general or specialised handbooks or into encyclopaedias after being accepted, integrated and shared by the scientific community.

**Summary**

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

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 of 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 protection of equivalents as integral to the concept of providing fair protection to the patentee. Others, such as the UK, deny that there is any room within Art. 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 Art. 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 the provision. 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”.

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**Art. 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, say, from 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, a 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 “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:

- Art. 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 – Art. 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” (docket no. 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 usually state that it is not appropriate to do so when asked) but nevertheless will concede to examining the file 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.
1. Claim construction – a history
2. The skilled person – an example
3. Purposive construction – with examples

1. Claims and the scope of protection under the EPC (history)

Before the adoption of the EPC, some European states adopted ‘peripheral claiming’ (e.g. the UK and Switzerland), and some adopted ‘central claiming’ (e.g. Germany and the Netherlands). 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, before 1977, 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 addressee reading the patent. This potentially extended protection was given on the basis that the inventor should be able to reap reward to the extent that the invention genuinely contributed to the art.
1977: Changes brought by the EPC – Art. 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 Art. 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.”

‘Peripheral’ claiming had won the day. Unfortunately however, the exact wording of Art. 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” vs “Inhalt der Patentansprüche” vs “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 Art. 69 EPC

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

In its original form (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

*Hereafter, the masculine shall include the feminine.
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 a diplomatic conference held in Munich in November 2000 (the Munich Conference), concern was expressed that Art. 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.

**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 word “terms”/“Inhalt”/“teneur” and the two words that followed it 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 to the 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 there is currently no common appeal court in Europe, and the EPO’s boards of appeal have jurisdiction only over the elements of patentability and process under the EPC, 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 member states.

2. 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.”

3. The UK approach to the construction of claims – purposive construction

Article 69 EPC is incorporated into UK law as s.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 s.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.”

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 substituted for 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 for 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 of 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 – s.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 (themselves) understand the words to mean, or even asking “what does this word mean to me?”

Context is critical to the analysis.

4. The German approach – *Schneidmesser I*

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.

**Further reading**

France has always been known for having a patent-friendly conception of infringement.

In a nutshell, a major step is to determine whether the claimed means differ from prior art only by a novel form (or structure) (these are called “particular means”) or by a novel function (these are called “general means”).

This distinction is intended to prohibit disguised infringements.

The infringement test described below is illustrated by the example of a claim covering a gardening tool.

1. 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 of the claims is usually discussed in the first part of French decisions, entitled “scope of the patent”.

This key step is governed by Article 69 of the European Patent Convention for the French designation of European patents and by Article L. 613-2 of the French Intellectual Property Code for French national patents; these two articles, which are identical, provide 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 defined by the decision issued
by the court of appeal of Paris on 11 October 1990 in the first case involving a European patent, in 1990 (Dolle v. Emsens), remains true:

“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 has 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 to the drawings.

He must give to the claim its full meaning, so that this condensed text is understood.

The construction leads to define the substance of the claimed invention, without adding any element which the claim did not include and did not suggest.”

The reference, in the above quotation, to the full meaning of the claim and to the substance of the invention shows that French judges do give a purposive construction of patents: they seek a fair balance ensuring both reasonable protection for the patentee and a reasonable degree of legal certainty for third parties.

When construing the claim, French judges seek to understand, with the eyes of the skilled person, the technical problem solved by the patent, the means taught to solve said problem and their function.

However, the construction of a claim must not result in adding to the claim a feature which it does not include ("interpreting is not adding") or, conversely, in omitting
a feature which it comprises.

The definitions provided in dictionaries, handbooks or other documents exhibited by the parties may be taken into account by the judges when seeking to understand the patent, but they must never prevail over the meaning stemming from the patent itself.

Such documents are used mainly to help clarify, when necessary, the knowledge of the skilled person and the way he would read and understand the patent.

Producing a written expert opinion is not excluded if it is indispensable to further clarify the documentary evidence and substantiate the knowledge of the skilled person; however, the use of expert opinions on this point is not usual in France.

The work done to understand the patent will also help the judges to distinguish further, if appropriate for the assessment of infringement:

- the features which should be considered as the so-called “essential means”, i.e. the features without which the claim would not be considered novel and inventive or the features without which the claimed means would not perform the function of the invention,

- the features which should be considered as minor (i.e. details) because they were not necessary for the claim to be novel and inventive and not indispensable for the claimed means to perform their function.

This analysis goes with the identification of the contribution of the invention to the art: the key idea is to understand whether the means taught by the patent differ from prior art only or mainly by some details of structure (or form) or whether 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, the *Cour de cassation* will quash decisions showing that the construction exercise led to distortion of the claim (either by adding or by omitting a feature) or to creation of a contradiction between the specification and the claim.

But the *Cour de cassation* will not review the technical findings of the *cour d'appel* about the knowledge of the skilled person.

The claims and the specification are construed at the patent’s filing date or priority date, if any.

The scope given to the claims is the same for validity and infringement, so that the so-called **Angora cat paradox** cannot apply.

### 2. The man 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, notably because the question whether the contested product was an obvious alternative is not relevant, as explained further in sections 3.3.5 and 3.3.6 below.

However, the person skilled in the art and his knowledge are taken into account for the construction of the claims and of the specification, as shown in section 1 above.

In any case, the skilled person is the same for all the purposes related to a same patent.

This person is a pure legal fiction, defined by the late Professor Jean-Marc Mousseron as “*a strange average technician having access to a vast amount of documents but with reasoning abilities limited to those of an average agent without any inventive capacity and with no ability to go beyond the obvious area*”

*Hereafter, the masculine shall include the feminine.*
surrounding his knowledge”.

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; it is also now clearly admitted that the skilled person may be a team when the technical problem solved by the patent is at the crossroads of several technical fields.

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, of a physicist in charge of determining the physical properties of the lenses and of a clinician ophthalmologist specialised 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 intermediate technician for a relatively simple technical field and a highly qualified specialist in a more complex case.

The knowledge of the skilled person includes all the knowledge of his technical field, the knowledge of neighbouring fields raising identical or similar problems, the general knowledge which is not specific to the relevant field (for example general mechanical knowledge) and common sense; but it does not include research data which is not yet validated; said knowledge is proved by documents, sometimes (but not frequently) with the help of a party’s expert opinion to clarify the meaning of documents exhibited by the parties.

The skilled person has the ability to make logical deductions and to perform routine operations as well as implementation work.

3. The French tests for infringement
The patent philosophy at the origin of the purposive construction described in section 1 above also leads French judges to a relatively broad conception of infringement by equivalence: this trend had suggested the metaphor “France vs. The rest of the world” in an article by Pierre Véron, which seems to remain true.

Infringing means were defined by Paul Mathély as those reproducing 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.

This broad approach is also reflected by the traditional formula “infringement is assessed by resemblances and not by differences”.

The French infringement test can be considered as threefold:

• (i) the first question is whether there is literal infringement, i.e. whether the contested means reproduce the claimed means both in their form (or structure) and function (3.1.),

• (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 (3.2.),

• (iii) if not, the third question is whether there is infringement by equivalence, which is the case when the claimed means perform a new function and if the contested means perform said function for the same results as the claimed means (3.3.).

For each of these steps, both the claimed and the contested means should be considered in terms of form (or structure) but also in terms of function (with the meaning of the primary technical effect) and results (with the meaning of the advantages provided by the

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“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.” (“Le nouveau droit français des brevets d’invention” by Paul Mathély, chapter II, section 1, page 413).
invention).

The explanation below will be illustrated by the example of a claim covering a gardening device.

The figures below show the claimed device and the contested one:

<table>
<thead>
<tr>
<th>Claimed device</th>
<th>Contested device</th>
</tr>
</thead>
<tbody>
<tr>
<td>![Claimed Device Image]</td>
<td>![Contested Device Image]</td>
</tr>
</tbody>
</table>

The patent at issue relates to a manual gardening device, comprising a handle at one end and a tool at the other end, for loosening the soil, mixing the soil layers and removing the weeds without great effort thanks to a helical movement.

Claim 1 covered the structure of the tool, and in particular the arrangement of its tines, with the following main characteristics:

- the tines envelop a virtual cylinder in the axis of the shaft,
- the tines form an angle alpha of 90°.

On the basis of the explanations provided by the description, the Court considered that the function of

Claim 1 reads:

"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 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 line feet (14 a” – d”) and line tips (14 a’ – 14 d’) with the axis of said shaft (11) form an angle of approximately 90°."
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.

3.1. Literal infringement

There is literal infringement ("contrefaçon à l'identique") when the contested means reproduce the claimed means in their form and their function for the same result.

However, most often, 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 in their function for the same result, since there was a difference notably relating to the angle alpha formed by the tines (which was 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, determining whether these differences relate to details or to essential means of the claim.

3.2. 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.

There is infringement by reproduction of the essential means of the claim when the differences shown by the contested means relate only to details, in other words minor features.

In fact, this question is also twofold:

- First, comparison of the claimed and infringed means will allow 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 only details (in which case there is infringement) or, on the contrary, 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 it presented as essential in the patent or in the prosecution? For example, does the patent mention alternatives?
- Is this feature one of those without which the claim would not have been found novel and inventive?
- Is this feature indispensable to fulfil the function of the claimed means and to solve the technical problem at the basis of the invention?

If the claimed means which are not literally reproduced turn out to be a minor feature (i.e. a detail), there is a final finding of infringement at this stage.

Otherwise, the work continues in order to determine whether there is infringement by equivalence.

When applied to the example of the gardening tool, this twofold test leads to the following conclusion: the contested device differs from the claim notably in that it has tines forming alpha angles smaller than 90°; this alpha angle of 90° was not a minor feature notably because it was important in the 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, this feature is essential 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, i.e. determining whether there is infringement by equivalence.

**3.3. Infringement by equivalence**

The question 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. Caposa): the fact that the patent precisely describes 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", i.e. "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.")

In a decision of the Tribunal de grande instance de Paris of 29 September 2004, 3rd chamber, 1st section (L'Oreal/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 the whole chemical reactions involved in the formation of the capsules: "That, 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;".
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 preliminarily ascertained that said function of the claimed means is novel.

Therefore the test for infringement by equivalence is threefold:

- Do the essential means of the patent whose form is not reproduced (hereafter “the means at issue”) perform a novel function (3.3.1)?

- If so, do the contested means perform the same function (3.3.2)?

- If so, do these contested means provide the same results (3.3.3)?

Tests applied in some other countries, such as the obviousness for the skilled person that the contested means were equivalent or the intention of the patentee, are not relevant in France (3.3.4).

3.3.1. Prerequisite: the claimed means at issue must perform a novel function

At the outset, it should be noted that the doctrine of equivalence is not necessary if the function is claimed per se, because in such a case, any means which perform this function will be held 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 may exist...
only if the claimed means at issue differ from 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 the key question is the contribution of the invention to the art when assessing whether infringement by equivalence can apply.

This rule has been applied by French judges for decades.

It is still applied in recent case law, as illustrated by the following 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 previously found that the claimed combination of means differs from prior art only by their form but 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 infringement by equivalence was excluded since 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 blockage 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 well-established French case law.

In the example of the gardening device, the question whether the claimed means (and, in particular, the tines with an alpha angle of 90°) implement a novel function led the court to study the prior art cited by the alleged infringer and examine whether this specific angle of 90° creates only a structural difference or a functional one over prior art.
The drawings below show the claimed device and three prior-art gardening tools:

<table>
<thead>
<tr>
<th>Prior art</th>
<th>Claimed device</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image1" alt="Prior art" /></td>
<td><img src="image2" alt="Claimed device" /></td>
</tr>
<tr>
<td><img src="image3" alt="Prior art" /></td>
<td><img src="image4" alt="Claimed device" /></td>
</tr>
<tr>
<td><img src="image5" alt="Prior art" /></td>
<td><img src="image6" alt="Claimed device" /></td>
</tr>
<tr>
<td><img src="image7" alt="Prior art" /></td>
<td><img src="image8" alt="Claimed device" /></td>
</tr>
</tbody>
</table>

The court considered that the function of the 90° alpha angle in the claimed device, i.e. rotating like a screw in the soil and loosening the soil, was not disclosed in prior art.

Therefore, the function of the claimed device, and notably of its alpha angle of 90°, was novel.

When the claimed feature, which is not literally reproduced, performs a new function, the judges have to move to the following part of the test, to determine whether the disputed means perform said function.
3.3.2. The contested means must perform the same function

Two means perform the same function when 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.

This distinction between function and result was particularly well explained in a decision of the Cour de cassation, Commercial chamber, of 26 January 1993 in a case 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 affirmed the judgment of the Cour d'appel de Paris, which had decided that the obtaining of 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.

Some old decisions further considered the way in which the contested means perform the function for the same results, but they do not seem to be followed.

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 checked that they provide the same result.

3.3.3. 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 higher 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".

3.3.4. 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 only when inventive step is assessed.

Therefore, the question whether the contested means are obvious for the skilled person is not relevant in France when assessing whether they constitute infringement by equivalence.

The lack of relevance of obviousness is confirmed by the French rule that improving the claimed means may be an infringement.

This solution used to be summed up in the formula: "Improving is infringing". However, this striking formula 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.
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 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 equivalent. Some French decisions do not explicitly describe each of the above steps and may use a slightly different wording.

However, the reasoning described above is that applied for decades in French case law, in order to give the claim its full scope.

4. Is there a doctrine of file wrapper estoppel?

Estoppel does not exist as such under French law, and the principle remains that the judges have no obligation to refer to the “file story” of the patent, as recalled, for example, in a decision of 23 November 2010 of the Cour de cassation, commercial chamber (Institut Pasteur v. Chiron).

However, it is not exceptional to find decisions taking 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 case of a contradiction in 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. Mr Gianffranco Tudo).

- It applies only in case 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 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;

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 for extending 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 referring to the file story of the patent taken as a fact, to clarify a point of the discussion.

It emerges from the above that French case law has a quite patent-friendly approach to equivalence.
Introduction

Determining the scope of protection of a patent is relevant not only with respect to establishing infringement, but also with respect to the assessment of 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. The Supreme Court 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 that the judge would give a broader explanation to the patent than

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 (Fruitsortingmachine); opinion of advocate general Franx at
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. 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 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) provided 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, however, did not immediately align their judgments with the uniform European provisions on the determination of the scope of protection.

It was argued by scholars that the Dutch opinion which was held until then had to give way to the European provisions on the determination of the scope of protection of European (national) patents. After all, Article 69 EPC should be applied when determining the scope of protection – instead of the national laws (see below).

It was only in 1995 that the Supreme Court slightly changed its approach as regards the determination of the scope of protection in the case Ciba Geigy v. Oté Optics. In this case, the Supreme Court, traditionally, took the essence of the invention as a starting point for establishing the scope of protection of a patent. The Supreme Court, however, clarified “the essence of the invention” by introducing a new wording, i.e. “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 in turn would provide scope for protection extending beyond the actual words of the claims.

In 2007, the Supreme Court made clear in its *Lely v. Delaval* decision that the essence of the invention is not to be considered 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 do not mention the essence of the invention as an important element in determining the scope of protection of European and national patents.

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 the skilled man from reading the descriptions comes to that conclusion, the extent of the protection conferred by the claims can even be more limited than might appear when reading the claims out.
of context.

Relevance of the prosecution file for determining the scope of protection

A defendant may rely on the prosecution file when arguing the scope of protection. The Supreme Court has ruled in Meyn v. Stork (1989) that third parties may assume that the patentee has wanted to limit himself by the chosen wording of the claims, if good reasons exist for that assumption having regard to the patent specification in the light of any other known data such as the prosecution file.

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).

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 risk. According to the Supreme Court, arguments from the prosecution file in favour of the patentee may be used with reluctance only. The defendant in infringement proceedings, however, may always derive arguments from the prosecution file.

In Saier v. Dijkstra (2006), the Supreme Court ruled that third parties are not limited in using arguments based on the prosecution file.

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

Hereafter, the masculine shall include the feminine.
patented invention to parties which are not entitled to use the patented invention (Article 73 DPA). 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. It is further required that the party supplying the means knows that those means are suitable and intended for application of the patented invention, or that such is evident in view of the circumstances.

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.

**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.

In its decision in the case *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 is out of question when application of the

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**Complementary reading: Dutch approach**

Court The Hague, 8 September 1998, *BIE* 1999, 244 (Rustibus);

Supreme Court of the Netherlands, 31 October 2003, *BIE* 2004, 47 with commentary from JdH (*Sara Lee v. Intergro*), para. 3.4.2.


See District Court The Hague, 28 October 1998 (*Yamanouchi v. Biogen*).

The most recent patent cases where the Dutch courts
alleged infringing process leads to a significantly inferior result.

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.

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 is directional. Within the framework of establishing infringement, besides 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.

Defences to infringement

In the Netherlands, the research exemption is laid down in Article 53(3) DPA. This article provides that acts solely serving 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.

According to the legislative history of the Dutch Patent Act, this research exemption must be interpreted restrictively. The research exemption is designed only for acts that exclusively serve for investigating the patented invention. It follows from the doctrine and case law that only research having a purely scientific acceptance in infringement by way of equivalence are: District Court The Hague, 31 March 2010 (*Erendam 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. Smilee*), para. 15-16, and Court of Appeal The Hague, 23 February 2006 (*Multifase Schroef-slippomp*), para. 33. In the last 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 defendant’s infringement claim (para. 4.4.1-4.5).

Accepted infringement by way of equivalence are: District Court The Hague, 31 March 2010 (*Erendam 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. Smilee*), para. 15-16, and Court of Appeal The Hague, 23 February 2006 (*Multifase Schroef-slippomp*), para. 33. In the last 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 defendant’s infringement claim (para. 4.4.1-4.5).

character is considered to fall under the research exemption. Market research or large-scale manufacture is not allowed. Further, performing clinical trials within the context of obtaining market authorisation for a generic medicinal product does not fall under the research exemption either.

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 provides that conducting the necessary studies, tests and trials within the context 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 the case Gillette v. Anglo American Trading Company, and has since been known as the ‘Gillette defence’.

This Gillette defence is acknowledged by the Dutch courts. In Dutch proceedings, the Gillette defence may also be applied in case of alleged ‘literal’ infringement – i.e. equivalence is not a condition. Examples of
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 only accepts applications under the EPC and the Patent Cooperation Treaty (PCT). If an applicant desires patent protection in only a small number of states, he* may be better advised to seek protection directly with the national offices. The national requirements for those states that contract to the EPC are identical to those under Art. 78 EPC.

Languages

Applications may be filed at the EPO in any language. However, according to Art. 14(2) EPC, applications made in any 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 of the Regulations requires a 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 (Art. 14(3) EPC). The specification of a 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 (Art. 14(6) EPC).

*Hereafter, the masculine shall include the feminine.
The role of the documentation in the 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, and elements of it will be used to determine the patent’s scope of protection. It is therefore the body of the patent itself. The specification will be examined in order to ensure that the patent’s subject-matter is new, inventive, etc. – i.e. that it fulfils the requirements of patentability. The specification also has a role to play in determining the patent’s scope of protection, as it houses 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 gives brief technical information about the disclosure as contained in the specification. Whilst the abstract is initially supplied by the applicant, the examiner is responsible for finalising its content (Rule 66 EPC).

The abstract’s role is solely to provide technical information in order to assist searching within the technical field in question. Its role in a search is to provide sufficient information to assess whether there is any need to consult the patent application itself. The abstract has no play to play in interpreting the patent’s claims (and therefore determining its scope of protection) – Art. 85 EPC.

Requirements for the abstract

Rule 47 EPC details 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
- preferably be 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. 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.

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; and
(f) indicate explicitly (where this is not obvious) the manner in which the invention is industrially applicable.

**Drawings**

The requirements as to the form and content of the drawings are set down 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 matters may be included on the drawings.
Claims – requirements

The claims are the heart of the patent. They define the invention, demarcating what is old from what is new, and 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” (Art. 78(1) EPC).

Since the extent of the protection conferred by a European patent or 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 – Art. 69(1) EPC.

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

Claim types and categories

There are only two basic categories of claims:

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

The claim’s category 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).

So-called “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, i.e. 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 EPO’s boards of appeal). 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. standing by themselves) or dependent (i.e. 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.

The claims must be clear and concise

The claims define the invention and dictate the patent’s scope of protection; accordingly, it is crucial that they are clear.

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

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 with the public’s benefit from the patent disclosure. This requirement is reflected in the demand of Art. 84 EPC for the claim to be “supported by the description”.

In the straightforward case, this means that it is impermissible for the patent to 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 EPO’s boards of appeal). 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.