

it is stated that the basic patentability considerations in respect of claims for computer programs are in principle the same as for other subject-matter. While “programs for computers” are one of the items listed in Article 52(2) EPC, if the claimed subject-matter has a technical character it is not excluded from patentability by the provisions of Article 52(2) and (3). Moreover, a data processing operation controlled by a computer program can equally, in theory, be implemented by means of special circuits, and the execution of a program always involves physical effects, e.g. electrical currents.

According to **T 1173/97**, such normal physical effects are not in themselves sufficient to lend a computer program technical character.

T 1173/97 (IBM computer program product)

However, if a computer program, when running, is capable of bringing about a further technical effect going beyond these normal physical effects, it is not excluded from patentability. This further technical effect may be known in the prior art. A further technical effect which lends technical character to a computer program may be found, for example, in the control of an industrial process or in processing data which represent physical entities or in the internal functioning of the computer itself or its interfaces under the influence of the program, and could, for example, affect the efficiency or security of a process, the management of the computer resources required or the rate of data transfer in a communication link.

As a consequence, a computer program may be considered as an invention within the meaning of Article 52(1) EPC if it has the potential to bring about, when running, a further technical effect which goes beyond the normal physical interactions between the program and the computer. A patent may be granted on such a claim if all the requirements of the EPC are met.

Moreover, following **T 769/92**, the requirement for technical character may be satisfied if technical considerations are required to carry out the invention. Such technical considerations must be reflected in the claimed subject-matter.

T 769/92 (General purpose management system)

Any claimed subject-matter defining or using technical means is an invention within the meaning of Article 52(1) EPC. Therefore, the mere inclusion of a computer, computer network, readable medium carrying a program, etc. in a claim lends technical character to the claimed subject-matter.

If the claimed subject-matter does not have a *prima facie* technical character, it should be rejected under Article 52(2) and (3) EPC. If the subject-matter passes the *prima facie* test for technicality, the examiner should then proceed to the questions of novelty and inventive step.

National approaches

The extent to which national case law on patentable subject-matter follows that of the EPO varies from country to country.

The Netherlands

The Netherlands Patent Office and the Netherlands courts follow EPO practice very closely. The patent courts in The Hague almost always explicitly apply the same patentability criteria as applied by the EPO. Thus, for example, in *Looijengoed v Dronrijp et al.*, even though decisions of the Boards of Appeal of the EPO are not strictly binding on the Netherlands Patent Office, when a third party raised an objection relating to non-patentable subject-matter, the Netherlands Patent Office stated that it would follow the case law of the patent courts in The Hague and the EPO.

Netherlands Patent Office
20.08.2010, BIE 2010, 19 (*Looijengoed v Dronrijp et al.*)

Germany

In Germany, in order to be patentable, an invention must have technical character. Technical character is considered to be present if an invention at least partially concerns some technical aspects. Examples include the embedding of a program in a technical device, the processing, storage and transfer of data via technical means, and where a processing system's elements interact directly with particular data. The mere use of a device or its components may be sufficient to fulfil the requirement of technical character, even if this only represents a partial technical aspect of an invention.

Bundesgerichtshof (BGH), German Federal Supreme Court, 22.04.2010, Xa ZB 20/08 – “*Dynamische Dokumentengenerierung*”

BGH, 26.10.2010, X ZR 47/07 – “*Wiedergabe topografischer Informationen*”

BGH, 17.10.2001 – “*Suche fehlerhafter Zeichenketten*”

BGH, 20.01.2009, X ZB 22/07 – “*Steuerungseinrichtung für Untersuchungsmodalitäten*”

BGH, 22.04.2010, Xa ZB 20/08 – “*Dynamische Dokumentengenerierung*”

Subject-matter excluded from patentability – programs “as such” – is examined more critically in addition to the more general requirement of technical character. Under established German case law, programs are only patentable if they are designed to solve a specific technical problem. Accordingly, the mere content of a program – the program “as such” – is excluded from patentability as not serving a technical function. Consequently, a patent's objective teaching is examined in order to rule out programs which do not solve a concrete technical problem. Based on a comprehensive survey of the claimed solution, the question is whether a patent's teaching serves to solve a concrete technical problem which goes beyond mere data processing. This is the case, for instance, if an external device is controlled by a computer program, requiring the consideration of conditions outside the data processing unit as part of the claimed teaching.

A concrete technical problem can be affirmed if device components are modified or addressed in a new way, or if a program is determined by external technical aspects. In the same way, the adaptation of a computer

program to the technical features of a computer may be deemed to be a technical solution. In other words, as a computer is a technical device, software tailored to its characteristics may have technical character.

France

If an invention does not involve a technical effect, the French Patent Office will reject an application on patentability grounds rather than declaring that the invention lacks inventive step (as is the practice at the EPO). Thus, for example, in **Sagem**, the Paris Court of Appeal confirmed a decision of the French Patent Office which refused to grant a patent for a method for electronically ordering products at a sales outlet, on the grounds that the technical effect requirement was not met and that the invention amounted to a business method. Similarly, in the **Catalina** rulings, the French courts held that an invention aimed at delivering coupons to customers was patentable, as long as what was claimed was a device characterised by a precise structure and defined by its features, which constituted its technical aspect.

Sagem, Cour d'appel (CA), Court of Appeal of Paris, 10.01.2003

Catalina, Tribunal de Grande Instance (TGI), Regional Court of Paris, 21.06.2002; confirmed by the CA Paris, 28.04.2004

United Kingdom¹

In **Merrill Lynch**, the Court of Appeal endorsed the then approach of the EPO, which had been established in *T 208/84 Vicom/computer-related invention* and which required, in the patentable subject-matter, the presence of a “technical” effect. This has remained the key test applied in the UK. This approach was endorsed by the Court of Appeal in 2006 in *Aerotel Limited v Telco Holdings Limited; Macrossans’ Patent Application* [2006] EWCA Civ 1371, where the Court set out the structured approach to assessing whether a claimed invention relates to patentable subject-matter shown on the right.

Merrill Lynch’s application [1989] RPC 561

UK Aerotel test for patentable subject-matter

1. Properly construe the claim.
2. Identify the actual contribution.
3. Ask whether it falls solely within the excluded subject-matter.
4. Check whether the actual or the alleged contribution is actually technical in nature.

Subsequently, in *AT&T Knowledge Ventures and CVON Innovations Limited applications* [2009] EWHC 343 (Pat), the English High Court provided further guidance on the correct approach to determining technical contribution under the *Aerotel* test. Noting that it was impossible to define the meaning of “technical” in the context of the *Aerotel* test, the Court identified a number of signposts as to what might be a relevant technical effect. These signposts were then subsequently endorsed by the Court of Appeal in a slightly modified form.

AT&T: Signposts for patentable subject-matter as amended by the Court of Appeal

- (i) whether the claimed technical effect has a technical effect on a process which is carried on outside the computer;
- (ii) whether the claimed technical effect operates at the level of the architecture of the computer, that is to say whether the effect is produced irrespective of the data being processed or the applications being run;
- (iii) whether the claimed technical effect results in the computer being made to operate in a new way;
- (iv) whether the program makes the computer a better computer in the sense of running more efficiently and effectively as a computer;
- (v) whether the perceived problem is overcome by the claimed invention as opposed to being merely circumvented.

¹ The EPC and the UK Patents Act 1977 (as amended) apply equally to all parts of the United Kingdom. Jurisdictionally, however, the United Kingdom is divided into three parts: England and Wales, Scotland, and Northern Ireland. Proceedings in the Scottish courts differ markedly from those in the other jurisdictions.

Other exceptions to patentability

In addition to the exclusions set out in Article 52(2) EPC, Article 53 EPC prohibits patents from being granted in respect of certain inventions. These exceptions to patentability do not result from the application of the traditional criteria (novelty, industrial applicability, and so on). Rather, they reflect political choices not to grant patents with respect to the specific subject-matter of those exceptions, even though such subject-matter would otherwise have been patentable.

Ordre public and morality

Traditionally, the exception to patentability resulting from **Article 53(a) EPC** was applied on the rarest of occasions only. However, in more recent times, this provision has become the basis for a specific body of law concerning biotechnological inventions.

Further definitions of inventions excluded from grant under Article 53(a) EPC are set out in Rule 28 EPC.

Point (c) of the list in **Rule 28 EPC** has been problematic and has given rise to case law, because it is the basis on which applications relating to human embryonic stem cells have been held not to be patentable. To the extent that such stem cells – or more generally the product that is the subject-matter of the claim – could, at the filing date, be exclusively obtained through the destruction of human embryos, it was held by the Enlarged Board of Appeal in **G 2/06** that Article 53(a) EPC made the claim unallowable.

With respect to biotechnological inventions, account must also be taken of EU Directive 98/44/EC of 6 July 1998 on the legal protection of biotechnological inventions. In a ruling of 18 October 2011 (**Oliver Brüstle v Greenpeace eV**), the Court of Justice of the European Union (CJEU) interpreted the Directive to exclude from patentability a process which involves the removal of a stem cell from a human embryo at the blastocyst stage, entailing the destruction of that embryo. According to the Court, the exclusion from patentability covers any process that involves the destruction of an embryo, defined broadly as any ovum capable of commencing the process of development of a human being, irrespective of its development stage and method of creation.

Plant or animal varieties or essentially biological processes

Article 53(b) EPC excludes from patentability, on the one hand, plant and animal varieties and, on the other, essentially biological processes for the production of plants or animals.

Article 53(a) EPC

European patents shall not be granted in respect of:
(a) inventions the commercial exploitation of which would be contrary to “ordre public” or morality; such exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States

Rule 28 EPC

Under Article 53(a), European patents shall not be granted in respect of biotechnological inventions which, in particular, concern the following:
(a) processes for cloning human beings;
(b) processes for modifying the germ line genetic identity of human beings;
(c) uses of human embryos for industrial or commercial purposes;
(d) processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes.

G 2/06 (Use of embryos)

Brüstle v Greenpeace, C-34/10

Article 53(b) EPC

European patents shall not be granted in respect of:

...
(b) plant or animal varieties or essentially biological processes for the production of plants or animals; this provision shall not apply to microbiological processes or the products thereof; ...

As to plant and animal varieties, this provision includes applications directed to a specific plant or animal variety, or to a multiplicity of such varieties.

However, inventions that can be applied to an indefinite number of individual varieties *are* patentable under Article 53(b) EPC. This was applied, for example, to claims directed to transgenic plants comprising in their genomes specific foreign genes, without however the plants being further defined.

G 1/98 (Transgenic plants/Novartis)

Essentially biological processes for the production of plants or animals are further defined by Rule 26(5) EPC.

Rule 26(5) EPC

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

It was held that the addition of further steps to the essentially biological process (e.g. a selection step based on genetic molecular technologies) does not change the fundamental nature of the process, such that it remains non-patentable. Conversely, a process that does not rely on “natural phenomena such as crossing or selection”, e.g. genetic engineering involving the artificial insertion of genetic material into a genome, does not constitute an essentially biological process for the purposes of Article 53(b) EPC.

G 2/07 (Broccoli/Plant Bioscience)

Methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body

Article 53(c) EPC is the provision that has led to the most difficulties, because it is directly relevant to the way in which companies active in the area of life sciences protect their innovations.

Article 53(c) EPC

European patents shall not be granted in respect of:

...

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

The intention behind this provision is to exclude non-commercial and non-industrial medical and veterinary activities from the claim. But as evidenced by the final portion of Article 53(c), that does not apply to products for use in surgical therapeutic methods (e.g. medicaments), which are definitely patentable.

Case law concerning the patentability of medicaments

The wording of Article 53(c) EPC confirms that products that can be used for the treatment of the human or animal body are patentable. However, questions arise as to the patentability of first and further medical uses of known compounds.

As far as such cases are concerned, it is clear from the wording of Article 53(c) EPC that a claim cannot be directed to the “use of compound X for the treatment of disease Y”, as this would be “*in no way different in essential content from a claim directed to a method of treatment*”. The Enlarged Board of Appeal of the EPO held that so-called Swiss-type claims, i.e. claims to the “use of compound X for the manufacture (or preparation) of a medicament for the treatment of disease Y”, were compliant with Article 53(c) EPC. This formulation could be used to protect first or subsequent medical uses of a known compound.

G 5/83 (Second medical indication)

While French case law had been somewhat unclear for a while, the decisions of the Enlarged Board of Appeal holding Swiss-type claims to be patentable under Article 53(c) EPC were uniformly accepted by the national courts.

Another question arose more recently from patent claims taking the Swiss-type form, but differing from the prior art not through the illness to be treated, but rather through the patient population or, frequently, through the dosage regime for administration of the medicament (e.g. a claim to the “use of compound X for the manufacture of a medicament for the treatment of illness Y, characterised in that a daily dosage amount of Z mg”).

In this respect, the Enlarged Board of Appeal held that such claims are directed to products for use in methods according to Article 53(c) EPC, such that they are allowable under that provision. The Board also held that, because of changes to the EPC provisions covering novelty, claims concerning further medical uses should no longer take the form of Swiss-type claims, but of purpose-limited product claims (e.g. “compound X for use in the treatment of illness Y”).

G 2/08 (Dosage regime)

National case law in this area is generally in line with that of the Enlarged Board. It is the position of the UK, German and Netherlands courts. Recent French case law has also followed this line.

Actavis UK Ltd v Merck & Co Inc [2008] EWCA Civ 444

BGH, 25.02.2014, X ZB 5/13, X ZB 6/13 – “Kollagenase I” and “Kollagenase II”

Merck Sharp & Dohme Corp. v Mylan B.V., Rechtbank Den Haag First Instance Court of The Hague, 23.04.2014

CA Paris, 30.01.2015, *Merck v Actavis*

Surgical methods

The scope of the exception from patentability concerning surgical methods is defined by the nature of the treatment rather than its purpose. As soon as a surgical step is performed, the method in issue is surgical, and hence excluded from patentability by **Article 53(c) EPC**.

Surgical steps correspond essentially to those types of intervention for which specific medical qualifications are required. Most of the time they will be invasive; conversely, most (although not necessarily all, e.g. ear piercing) invasive operations are considered to be surgical.

Importantly, as soon as a method recites one surgical step, the exclusion from patentability resulting from Article 53(c) EPC applies, even if the other steps are not surgical.

Article 53(c) EPC

European patents shall not be granted in respect of:

...

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

The skilled addressee and common general knowledge

The skilled person/notional skilled addressee

There are two concepts in the law of patents which are extremely important to all aspects of patent litigation. The first is the “person skilled in the art”, sometimes known as the “skilled addressee”. The second is the “common general knowledge” of the art which this person is deemed to possess.

The first thing to note is that this person is hypothetical, a flexible construct. Patents are not addressed to the public in general, for example, or even to lawyers. They are practical documents, addressed to people who know what they are doing in a particular technical field. The person skilled in the art is deemed to be such a person.

Likewise, many questions concerning validity, particularly obviousness and sufficiency, are assessed through the eyes of this notional person. The person skilled in the art is referred to in Articles 46, 83 and 100 EPC.

Judgments in the field of patents frequently establish what in the case would be the attributes of the skilled person and to the extent of his knowledge (see “Common general knowledge” below).

Disputes frequently arise as to the attributes of the skilled person and the nature of the relevant art. These attributes will vary from case to case, and evidence may be produced to help determine who the skilled addressee is. In some areas of technology, the level of qualification may be high. Caution must, however, be exercised when differentiating the skilled person from any experts called to give evidence and the temptation to equate an expert witness (i.e. a real person) to the notional person.

The skilled person may also be a team of persons. For example, in the field of colour television two sciences are involved, electronics and colorimetry, and the court has assumed in such cases that the skilled person will be a composite team from those two fields working together. In the pharmaceutical field, the team is often comprised of a chemist/biochemist, a medical expert and a pharmacist. The attribute of hard work is also assumed to be present; the skilled person has “a will to make something work”. He is competent with workshop techniques. He may be presumed to have at his disposal a reasonable level of external (e.g. laboratory, library or mechanical) support and will have access to standard textbooks in the field. Patent specifications do not, however, usually form part of this working equipment, unless they are universally well-known.

Above all, the skilled person, whether an individual or a team, is always assumed to be non-inventive. He is unimaginative and incapable of a “scintilla of invention”. He will make use of the common general knowledge which he is assumed to possess. But he will always be an intelligent “plodder” or, as one well-known patent judge said, a “nerd”. Nor will he ever be at the top of his profession.

The attributes of the skilled person may be assessed at different times. For some purposes, e.g. obviousness, the relevant date will be the priority date. For other purposes it will be the date of publication of the document. This may be of some consequence in a rapidly moving technology.

Common general knowledge of the art

The common general knowledge of the art can be defined as the information which, at the date of the patent in question, is common knowledge in the art or science to which the alleged invention relates so as to be known to duly qualified persons of ordinary skill and experience engaged in that art or science. It has often been said that it is part of the mental equipment of a competent but not overly bright person working in the field in question. The knowledge must be “commonly and generally known”.

There is a difference between common general knowledge and what may be “public knowledge”. Even a well-known scientific paper may not be common general knowledge. It is in fact a common-sense notion derived from what would be known to a man good at his job but no more, at the relevant time. However, today, where access to the delivery of information through computer sources is available to all, deciding what was in fact common general knowledge at a particular time in the past may present the court with some problems.

The common general knowledge will be the subject of evidence in each case and may often form common ground between the parties. The evidence required is usually given by experts as part of their job in educating the court in the technology. It is often supported by references to standard textbooks.

Substantive grounds for invalidity

Extension of subject-matter

It is almost inevitable that claims are amended during prosecution. There may be a number of reasons for such amendments, including the need to adapt the claims of a Patent Cooperation Treaty (PCT) application to European formatting, the need to overcome prior art that was identified further to the filing of the application and/or the desire to adapt the claims to the marketed products.

Claims may also be amended after the patent has been granted, either in opposition/appeal proceedings, where the patent proprietor may elect to defend his patent in a modified form compared with that initially granted, or upon the patent proprietor's own initiative (post-grant limitation/ amendment; see below).

G 1/93 (Limiting feature)

Since such changes modify the scope of protection of the patent, and hence the legal situation of third parties, rules have been enacted to protect the rights of such third parties. Their purpose is *“to create a fair balance between the interests of applicants and patentees, on the one hand, and competitors and other third parties on the other”*.

Article 100(c) EPC – The subject-matter of the patent extends beyond the content of the application as filed: “added matter”

Article 138(1)(c) EPC states that a European patent may be revoked if *“the subject-matter of the European patent extends beyond the content of the application as filed or, if the patent was granted on a divisional application or on a new application filed under Article 61, beyond the content of the earlier application as filed”*. Identical wording in Article 100(c) EPC makes the same motive a ground for opposition against a European patent, while **Article 123(2) EPC** addresses in a general manner against “added matter” by amendment that *“the European patent application or European patent may not be amended in such a way that it contains subject-matter which extends beyond the content of the application as filed.”*

Article 138(1)(c) EPC

Article 123(2) EPC

The fundamental idea underlying these provisions is that *“an applicant shall not be allowed to improve his position by adding subject-matter not disclosed in the application as filed, which would give him an unwarranted advantage and could be damaging to the legal security of third parties relying on the content of the original application.”*

G 1/93 (Limiting feature)

This ground of nullity is commonly referred to as “added matter”.

Scope of application and test

Amendments that must be reviewed are any changes made to the specification except for additions to the specification that consist of references to the prior art, drawings and/or claims, compared with the application as filed. In practice, most of the issues that arise concern amendments to the claims.

Importantly, these provisions apply to all amendments made to the patent, whether during prosecution or opposition/appeal proceedings, or in voluntary post-grant limitation proceedings.

The UK courts have formulated this test as follows: *“the essential task for the court is to consider the disclosure of the [application as filed] and the Patent and to ask whether any subject-matter relevant to the invention has been added whether by deletion or addition. The comparison is a strict one. Subject-matter will be added unless it is clearly and unambiguously disclosed in the [application as filed].”*

Guidelines for Examination
H-IV, 2.2

The test is to determine whether the skilled person is presented with information which is not directly and unambiguously derivable from that previously presented by the application, even when account is taken of the matter which is implicit to the person skilled in the art.

Virgin Atlantic Airways Ltd v Premium Aircraft Interiors [2010] RPC 8 at para 67

The application as filed

Any assessment of the admissibility of an amendment thus requires a comparison of the subject-matter of the patent with the application as filed, to determine whether the technical information present in the patent can already be found in the application. This raises the question of how to identify the content of the application as filed.

BGH, 22.12.2009, X ZR 27/06 –
“Hubgliedertor I”

Identification of the relevant application

The relevant application is the application **as filed**, that is, the application initially filed by the patentee, including its specification, drawings and claims. It is not the priority application: a comparison between the priority application and the patent claims may be relevant for the entitlement to priority but not for the provisions on added matter.

For PCT applications, amendments are possible in the PCT phase, before the application enters the European phase. The application to be considered in such situations is the original application, before it was amended in the PCT phase. That application is normally published as a WO document.

Content of the application as filed

The provisions on added matter do not require all the features of the subject-matter of the patent to find literal support in the application as filed. Rather, it is permissible to include, for example in the claims, features that are implicitly – but yet clearly and unambiguously – disclosed in the application as filed as read and understood by the person skilled in the art (see below). It is important to note that this does not

allow one to assume that all elements that would be obvious to the skilled person in light of the application as filed would form part of its teaching. Rather, the test is whether the features in issue are clearly and unambiguously implied by the application as filed.

Features that are not present in the application *stricto sensu*, but only in documents referred to in the application, or in the priority application, are, as a general rule, not considered to form part of the disclosure of the application as filed.

The application as filed must be considered from the perspective of the skilled person, to whom it is directed, at the date of filing, and as a whole (i.e. looking at the teaching of the document in its entirety, including the specification, claims and drawings).

Examples of inadmissible added matter

A number of aspects of this general rule have given rise to disputes. One established principle is that the content of an application may not be considered to be a reservoir from which features pertaining to separate embodiments of the application can be combined in order artificially to create a particular embodiment. Indeed, in such a situation, the skilled person, reading the application, would not consider the particular combination of features in issue to form part of its teaching.

Another principle is that it is normally not permissible to generalise the teaching of the application beyond its content. For example, an application concerning “diesel engines” cannot be generalised to “combustion engines” if that does not form part of what the skilled person would directly and unambiguously derive from the application.

Conversely, it is not possible to specify the teaching of the application beyond its content. Hence, if the application concerns “combustion engines” generally, without any specification or exemplification of the type of engine, a claim may not include a feature restricted to “diesel engines”.

Because drawings form part of the application as filed, the teaching contained in them can support an amendment of the claims consisting of an inclusion of features derived from the drawings. Again, the basic criterion is that, when looking at the drawings, the skilled person is able to directly and unambiguously derive the feature in issue.

One very important question is the extent to which features can be isolated from a particular embodiment described in the application as filed, to be claimed in isolation from the other features of that embodiment. This is known as intermediate generalisation. As a rule,

G 3/89, 19.11.1992

Amendments are permissible only “within the limits of what a skilled person would derive directly and unambiguously, using common general knowledge and seen objectively and relative to the date of filing, from the whole of these documents as filed.”

BGH, 16.12.2008, X ZR 89/07 – “Olanzapin”

T 296/96 (Carboxamides/Shell)

T 1206/01 (Isostanol/Raisio Benecol)

ECB v DSS, TGI Paris, 09.01.2008

Protomed BV's Application [1983] FSR 110

BGH, 18.02.2010, Xa ZR 52/08 – “Formteil 296/96”

intermediate generalisations are permissible only if the skilled person, reading the application as a whole, would understand that the feature in issue can be isolated from the other features relating to that particular embodiment. That may in particular be the case if there is no structural or functional relationship between those features.

Abbott Laboratories Ltd v Evysio Medical Ltd
[2008] RPC 23

BGH, 29.09.2011, X ZR 109/08 –
“Sensoranordnung”

Article 123(3) EPC – The claims of the patent have been amended post-grant in such a way as to extend the protection conferred

Article 123(3) EPC has a very different scope of application compared with the provisions on added matter considered above. It applies only to amendments to the patent after grant, i.e. in opposition/appeal proceedings or further to a limitation. It has no application to amendments made during prosecution prior to grant of the patent.

G 1/93

“Article 123(3) EPC is directly aimed at protecting the interests of third parties by prohibiting any broadening of the claims of a granted patent, even if there should be a basis for such broadening in the application as filed.”

As from the date of publication of the grant of the patent, its claims as granted retrospectively determine the scope of protection given (Article 69(2) EPC). Third parties should therefore be able to rely on the scope of these claims as granted. Legal certainty of the patent requires that the scope of protection offered by the patent must not be extended after grant.

Importantly, the provisions of Article 123(3) EPC would bar such amendments, even if they otherwise had a basis in the application as filed, and hence complied with the provisions on added matter considered above.

Terms of comparison

The application of Article 123(3) EPC requires a comparison to be made between two matters. These are on the one hand the patent claims as amended after grant, and on the other, the set of claims as granted.

Where a patent undergoes a series of post-grant amendments (e.g. in opposition or appeal proceedings or within the framework of a voluntary limitation), the version of the patent to be considered is the set of claims resulting from the immediately preceding amendment. In other words, each consecutive amendment must comply with the rule of Article 123(3) EPC, such that the claims of the patent may not have a broader scope than **any** of the post-grant set of claims.

Importantly, the scope of protection offered by the set of claims (as granted and as amended) must, pursuant to Article 69(1) EPC and the Protocol on the Interpretation of Article 69, be determined using the description and the drawings. This means that, if it modifies the interpretation of the claims, an amendment to the description may contravene Article 123(3) EPC, even though the wording of the claims remains unchanged.

Test to be applied

The test to be applied to determine whether there has been a contravention of Article 123(3) EPC is simple. Article 123(3) EPC has not been complied with if, after amendment, there are embodiments that fall within the scope of the patent even though they would not have infringed the patent as granted.

Interaction between the provisions on added matter and Article 123(3) EPC

The provisions on added matter and those of Article 123(3) EPC are in principle to be applied separately and cumulatively: compliance with one set of provisions does not make contravention of the other allowable.

There is, however, one particular situation in which Article 123(2) and (3) EPC place the patentee in an “inescapable trap”. That is where, before grant (e.g. during prosecution, to overcome cited prior art), a feature is introduced into the claim which, after grant (e.g. during opposition proceedings), is considered to constitute impermissible added matter under Article 123(2) EPC. Compliance with Article 123(2) EPC would require removing the feature in issue from the patent claim. However, to do so would directly contravene Article 123(3) EPC, since removing a limitation from the claim would *ipso facto* extend its scope. The patentee can thus find himself in a situation where he cannot save his patent through any type of further amendment – hence the “inescapable trap”.

This can be illustrated with a practical example. Let us imagine a patent application directed to a combustion engine with some features, and prior art disclosing relevant petrol engines. The patentee might be tempted, during the examination procedure, to limit his claim to diesel engines in order to differentiate his patent over the prior art. However, if the patent is granted with a claim limited to diesel engines, there might then be an opposition challenging its validity on the grounds that the application as filed would not disclose diesel engines, such that the amendment to the claim would contravene Article 123(2) EPC. The patentee might be tempted to overcome this objection by removing the feature “diesel engines” from the claim, to return to combustion engines in general. This would address the Article 123(2) EPC concern, but would result in the fact that certain embodiments – petrol engines – would now be infringing the claim, whereas they would not have infringed the patent as granted. That would be contrary to Article 123(3) EPC.

In such situations, unless the patentee finds support in the description for another amendment that is both compliant with Article 123(2) EPC and more restrictive than the scope of the patent as granted, he cannot save his patent.

Novelty

Lack of novelty is one of the grounds for revocation of European patents (Article 138(1)(a) EPC).

According to **Article 54(1) EPC**, “an invention shall be considered to be new if it does not form part of the state of the art.” The state of the art comprises everything made available to the public (anywhere in the world), whether by written or oral description, by use or in any other way, before the filing or priority date of the application. Since the entry into force of the EPC 2000, for the assessment of novelty (but not obviousness), the state of the art includes the content of all European patent applications having an earlier priority date but published after the application in question (i.e. co-pending patent applications). A co-pending PCT application may also form part of the state of the art as long as it is published in one of the official languages of the EPO, or its translation into one of these languages is filed with and published by the EPO, and the fee for entering the regional phase to prosecute the application before the EPO is paid.

The rationale of considering unpublished patent applications is to try to prevent “double patenting” in systems such as the EPO which follow the “first-to-file” rule. A party seeking to rely on an unpublished patent application will have to prove (a) disclosure and enablement (more on this below), (b) that the disclosure is in the prior art application both as filed and as published, and (c) that the prior application is entitled to an earlier priority date.

It is sufficient for the prior art to be “available to the public”, regardless of the language (which is irrelevant), even if nobody has actually read it. However, a confidential document or a document disclosed in breach of a confidentiality obligation may not be considered as being available to the public.

No combinations (“mosaicing”) allowed

Unlike inventive activity, when considering novelty it is not admissible to combine separate items of the prior art. It is not even admissible to combine separate items pertaining to different embodiments described in one single document, unless such combination has been specifically suggested.

Article 54 EPC

Novelty

(1) An invention shall be considered to be new if it does not form part of the state of the art.

(2) The state of the art shall be held to comprise everything made available to the public by means of a written or oral description, by use, or in any other way, before the date of filing of the European patent application.

(3) Additionally, the content of European patent applications as filed, the dates of filing of which are prior to the date referred to in paragraph 2 and which were published on or after that date, shall be considered as comprised in the state of the art.

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

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

T 108/01 (Dialysis machine with safety monitoring)

T 305/87 (Shear)

Two-limb test

The prior art destroys novelty if it discloses the claimed invention and enables the skilled person to perform it using only his common general knowledge. So for the novelty attack to succeed, the party seeking to revoke the patent must prove two separate facts: (a) that the invention is disclosed in the prior art, and (b) that the disclosure is enabling.

Meaning of disclosure: explicit and implicit disclosures

A claimed invention will lack novelty if it is explicitly or implicitly disclosed in the prior art. In particular, a document would destroy novelty if the claimed invention were directly and unambiguously derivable from the document, including any features implicit to the skilled person in what is expressly mentioned in the document (“clear and unambiguous directions”). The classical example cited in the Guidelines for Examination in the EPO is that a disclosure of the use of rubber in circumstances where clearly its elastic properties are used, even if this is not explicitly stated, takes away the novelty of the use of an elastic material.

Guidelines for Examination
G-VI, 1

However, unlike inventive activity, when considering novelty, it is not admissible to interpret the teaching of the prior art as embracing equivalents which are not disclosed as such. So the claimed invention must be disclosed as such, explicitly or implicitly. It will be considered to be implicitly disclosed if, when carrying out the teaching of the prior art, the skilled person would inevitably arrive at a result falling within the claim (doctrine of the inevitable result). According to the Boards of Appeal of the EPO, this doctrine must be applied with caution. It requires the party seeking to revoke the patent to prove that the probability of arriving at a result falling within a claim, carrying out the teaching of the prior art as such, that is, without making any adaptations, is 100%. In particular, experiments aimed at questioning novelty must not deviate from the disclosure.

Time of interpretation

Interpretation of the disclosure is by reference to the knowledge of the skilled person in the field at the relevant date. A prior art document must be construed as it would have been construed by the skilled person at the date on which it was published. In the case of unpublished documents (**Article 54(3) EPC**), the relevant date is the date of filing or the priority date, where appropriate.

T 396/96 (Technip)

Article 54(3) EPC Novelty

Additionally, the content of European patent applications as filed, the dates of filing of which are prior to the date referred to in paragraph 2 and which were published on or after that date, shall be considered as comprised in the state of the art.

Purpose irrelevant

The purpose of the prior art disclosure is irrelevant for the assessment of novelty. So a disclosure in an unrelated technical field, which may be directed at a completely different technical problem, may still constitute an “accidental” anticipation (even if the same disclosure would be irrelevant for the assessment of inventive step).

Exclusions from the state of the art

Article 55(1) EPC provides for a limited six-month “grace period” for disclosures made in consequence of “an evident abuse in relation to the applicant or his legal predecessor” (e.g. where a disclosure is made in breach of a duty of confidence owed to the inventor) or for disclosure of an invention at officially recognised international exhibitions.

A generic disclosure does not anticipate a specific example

A generic disclosure does not normally destroy the novelty of any specific example falling within the terms of that disclosure. On the contrary, a specific disclosure normally destroys the novelty of a generic claim comprising such disclosure.

Selection inventions

An invention may consist of the selection of individual elements, species, sub-sets or sub-ranges from a wider known gender, set or range. A classic case, which concerns chemical inventions, is **T 12/81**, “selection inventions”. The Board of Appeal held that a selection from a single list of specifically disclosed elements does not normally confer novelty. However, if two classes of starting substances are required to prepare the end products, and examples of individual entities in each class are given in two lists of some length, then a substance from the reaction of a specific pair from the two lists can nevertheless be regarded as a selection and, therefore, new.

Unfortunately, EPO case law does not clarify how long such lists should be. This has to be determined taking into account the specific circumstances of each case and the technology involved.

Second medical use claims

Substances already known to have been used in a first medical use may still be patentable under **Article 54(5) EPC** for any second or further use in a method according to Article 53(c) EPC, provided that such use fulfils the novelty and inventive activity requirements.

Such claims must be carefully drafted. For example, a claim in the form “Use of substance X for the treatment of disease Y” will not be patentable, as it will be regarded as seeking to protect a method of treatment, which is excluded from patentability (Article 53(c) EPC). On the contrary, a claim in the form “Substance X for use as a medicament” would be admissible, as long as the use of substance X as a medicament was not known. A claim in the form “Substance X for use in the treatment of disease Y” would also be patentable, provided that such use fulfilled the novelty and inventive activity requirements.

Article 55(1) EPC

Non-prejudicial disclosures

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

(a) an evident abuse in relation to the applicant or his legal predecessor, or

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

T 12/81 (Diastereomers)

Article 54(5) EPC

Novelty

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

According to decision **G 2/08**, the treatment of a disease with a substance or composition which is already known to be used for treating such disease, where the only difference from the known treatment is in the dosage regime, is a specific further medical use within the meaning of Article 54(5) EPC. Therefore, according to G 2/08, which is the main reference in this field, therapeutic uses of a substance or composition may be based not only on the treatment of a different disease, but also on the treatment of the same disease by a different therapeutic method differing by parameters such as the dosage or administration regime, the group of patients or the route of administration.

G 2/08 (Dosage regime)

At present, the EPO only admits a claim in the old “Swiss-type” form (e.g. “Use of substance or composition X for the manufacture of a medicament for therapeutic application Z”) if such claim is new and inventive and is included in an application having an application or priority date before 29 January 2011.

Second non-medical use claims

A claim to the use of a known compound for a particular second non-medical use which is based on a technical effect should be interpreted as including that technical effect as a functional technical feature. Therefore, according to **G 2/88**, such claim would be patentable as long as said technical feature had not previously been made available to the public.

G 2/88 (Mobil/Friction reducing additive)

Stringent test

The test for novelty is a stringent one. For a disclosure or prior use to anticipate a claim it must disclose all of the features of the claim (i.e. only if the invention disclosed by the prior art would infringe the claim in question, if performed post-grant, will it deprive that claim of novelty). The test is not simply that the prior product or process was available to the public, but that the information conveyed by that product or process made the invention available. The limits of novelty are illustrated by decision G 2/88, in which a proposal to use an additive as a rust inhibitor was not held to anticipate the use of the same additive as a lubricant, even though the use of the additives in question for the known purpose would necessarily have achieved the new use as well.

Inventive activity: obviousness

Lack of inventive activity, also called inventive step, is another of the grounds for revocation of a European patent (Article 138(1)(b) EPC).

An invention is considered to involve an inventive step if, having regard to the state of the art, it would not have been obvious to a person skilled in the art. For the purposes of considering inventive step and in contrast to the assessment of novelty, later-published European patent applications

Article 56 EPC

Inventive step

An invention shall be considered as involving an inventive step if, having regard to the state of the art, it is not obvious to a person skilled in the art. If the state of the art also includes documents within the meaning of Article 54, paragraph 3, these documents shall not be considered in deciding whether there has been an inventive step.

are not considered to form part of the state of the art. The state of the art may reside in the relevant common general knowledge.

If anything in the claim is obvious, then the whole claim is invalid.

Problem/solution approach

The EPO and the courts of countries such as Germany and Spain normally follow the so-called “problem/solution approach” when assessing inventive step. Although application of this test is not compulsory, it is widely used, as it is aimed at reducing the risk of the inventive step being tainted by hindsight.

T 939/92 (Triazole)

The relevant dates for assessing whether or not the invention would have been obvious are of course the application date and, where the application claims priority from previous documents, the priority date of such documents. If different claims have different priority dates, then each claim has to be examined taking into account the respective priority date.

Problem/solution approach

1. Determine the “closest prior art”.
2. Establish the “objective technical problem” to be solved.
3. Consider whether the claimed invention, starting from the closest prior art and the objective technical problem, would have been obvious to the skilled person.

Closest prior art

The “closest prior art” is the one single prior art reference which discloses the combination of features which constitutes the most promising starting point (“springboard”) for an obvious development leading to the claimed invention. The process of identifying the closest prior art normally starts with a search for a reference directed to a similar purpose or effect and/or belonging to the same technical field or a technical field closely related to that of the invention. It is normally that which corresponds to a similar use and requires the minimum structural and functional modifications to arrive at the claimed invention.

T 632/02 (Thread formation)

Technical problem

Once the “closest prior art” has been identified, any technical effects which flow from the differences between a claimed invention and the closest prior art are then identified and used to establish the “objective technical problem” which the claimed invention may be said to solve. According to the EPO, the “technical problem” means the aim and task of modifying or adapting the closest prior art to provide the technical effects that the invention provides over the closest prior art. The expression “technical problem” does not imply that the technical solution must necessarily be an improvement over the prior art. It may simply be a new alternative solution.

T 606/89 (Particulate detergent composition)

Guidelines for Examination
G-VII, 5.2

The so-called “objective” technical problem may or may not coincide with the “subjective” technical problem that the applicant has revealed in the application. After the patent has been granted, it is legitimate for the patentee to reformulate the technical problem within the context of

T 92/92 (Valmet Paper Machinery)

T 495/91 (Oberflächenausrüstung/
PEGULAN)

litigation, particularly in view of new art asserted against the invention. For the purpose of reformulating the technical problem, any effect provided by the invention may normally be used as a basis, as long as such effect is derivable from the application as filed. The EPO also accepts reliance on new effects submitted by the applicant subsequently during the proceedings, as long as the skilled person would recognise such effects as implied or related to the technical problem initially suggested.

The technical problem must be carefully defined so as to avoid including pointers to the solution, as this would result in an *ex post facto* analysis and be contrary to EPO case law.

In establishing the objective technical problem, only differences which can be said to achieve a “technical effect” or lend an invention “technical character” are considered. Non-technical features and non-technical benefits such as purely economic benefits are ignored when formulating the objective technical problem. This is because the EPO considers that deriving such benefits is not the solution to a technical problem, so they are considered incapable of supporting an arguable technical inventive step.

At the EPO, this is achieved by formulating the objective technical problem from the perspective of a person skilled in the art who is aware of the non-technical aspects of the invention.

Could/would approach

Having formulated the objective technical problem, the final stage of the problem/solution approach involves assessing whether there is any teaching in the prior art as a whole that would have prompted the skilled person faced with the objective technical problem to modify or adapt the closest prior art to arrive at the claimed invention. In making this final assessment, the test applied is not merely whether a skilled person *could* have arrived at the claimed result but rather whether or not he *would* have done so in the hope of solving the objective technical problem or achieving some improvement or advantage (“could/would” approach).

The EPO Guidelines for Examination, following EPO case law, warn against an *ex post facto* analysis when assessing inventive step. Another general principle followed by the EPO is that a solution is obvious if it is established that the skilled person would have followed the teaching of the prior art with a “reasonable expectation of success”.

T 184/82 (Poly (p-methylstyrene) articles)

T 13/84 (Reformulation of the problem)

T 162/86 (Plasmid p SG2)

T 386/89 (Tractor wheel)

T 229/97 (Atorvastatin/Warner-Lambert)

T 229/85 (Ätzverfahren)

T 99/85 (Diagnostisches Mittel)

T 322/86 (Robert Bosch)

T 931/95 (Pension benefits)

Guidelines for Examination
G-VII, 8

“It should be remembered that an invention which at first sight appears obvious might in fact involve an inventive step. Once a new idea has been formulated, it can often be shown theoretically how it might be arrived at, starting from something known, by a series of apparently easy steps. The examiner should be wary of *ex post facto* analysis of this kind. When combining documents cited in the search report, he should always bear in mind that the documents produced in the search have, of necessity, being obtained with foreknowledge of what matter constitutes the alleged invention. In all cases he should attempt to visualise the overall state of the art confronting the skilled person before the applicant’s contribution, and he should to seek to make a “real-life” assessment of this and other relevant factors [...].”

T 2/83 (Simethicone tablet)

T 90/84 (American Cyanamid)

T 7/86 (Xanthines)

T 249/88 (Monsanto)

T 1053/93 (Detergent composition/
Unilever)

Other possible tests

As mentioned, the problem/solution approach is not the only possible method to assess inventive activity. The UK courts, for example, take a different approach. This is due in part to the availability of expert evidence, which is tested under cross-examination to assist the court with its determination of what would actually have been obvious to a person skilled in the art at the relevant priority date. The current test was developed by the Court of Appeal in *Windsurfing v Tabur Marine* [1985] RPC 59 CA and restated in a slightly re-ordered form in *Pozzoli SpA v BDMO SA* [2007] EWCA Civ 588.

Unlike at the EPO, where inventive step is assessed based on a single identified closest piece of prior art, any suitable item of prior art can form the starting point for assessment of inventive step. The assessment of inventive step is then a factual enquiry based on the evidence before the court as to differences between the claimed invention and a particular item of prior art and the common general knowledge of the relevant person skilled in the art. Such an assessment is purely factual and is not dependent on the formulation of a technical problem which can be said to have been solved by the invention, as the presence of a “technical contribution” for the basis of a patent is assessed separately as part of the test for patentable subject-matter.²

Relevance of expert evidence

Since the determination of inventive activity requires a decision on whether or not the invention would have been obvious to the skilled person, the examination and cross-examination of experts is very important in the courts of member states such as the United Kingdom and Spain. Experts are usually independent of the litigating parties and are often academics. In such countries, the court makes a careful assessment of the background and experience of the expert to ascertain whether they are suitable to assist the court in determining factual aspects of the case, and expert evidence normally has a key influence on the outcome of the case. In contrast, in countries such as Germany and France, it is not usual for the courts to hear the oral evidence of experts.

Secondary indicia

Both the EPO and the national courts consider factors such as the overcoming of a technical prejudice, the age of the documents asserted against inventive activity, the commercial success of the invention, the long-felt need of a solution to the problem solved by the invention, the contemporary reaction (for example, quick imitations or granting of licences) to the invention, the simplicity of the solution and/or an unexpected (bonus) effect as “secondary” indicia that may (or may not) reinforce the presence of inventive activity. However, such indicia are not

Windsurfing test as restated in Pozzoli

1. Identify the notional ‘person skilled in the art’ and the relevant common general knowledge of that person.
2. Identify the inventive concept of the claim in question or, if that cannot readily be done, construe the claim.
3. Identify what, if any, differences exist between the matter cited as forming part of the ‘state of the art’ and the inventive concept of the claim or the claim as construed; and viewed without any knowledge of the alleged invention as claimed, decide whether those differences constitute steps which would have been obvious to the person skilled in the art or whether they require any degree of invention.

- T 79/82 (System- & Verfahrenstechnik)
- T 109/82 (Hearing aid)
- T 181/82 (Spiroverbindungen)
- T 192/82 (Formassen)
- T 106/84 (Packing machine)
- T 229/85 (Ätzverfahren)
- T 295/94 (Double flow valve)
- T 848/94 (Polyamide film)

² As noted above, “mosaicing” of prior art documents may be permissible when assessing inventive step.

of course a substitute for the assessment of inventive activity described above. The presence of such indicia serves to reassure the court on the conclusions stemming from such analysis. They may be particularly useful in case of doubt.

Relevance of a general technical prejudice

One of the indicia that normally carries more weight is the existence of a technical prejudice. In particular, according to EPO case law, inventive activity can sometimes be established if it is shown that the solution overcame a general technical prejudice (i.e. a widely held but incorrect opinion of a technical fact). The existence of such prejudice should normally be proven either by reference to the literature published before the priority date or by expert evidence.

Selection inventions

As mentioned in the section dealing with novelty, a selection invention represents a sub-set, sub-range or sub-class from a wider group. Such a selection may be inventive when is connected to a particular technical effect and there are no hints in the prior art leading the skilled person to make that selection. The technical effect may, for example, be an unexpected improvement or the same effect attained within the broader known range, but to an unexpected degree.

Non-technical inventions

When assessing inventive step, it is EPO practice to reject applications which do not solve a “technical” problem, the reason being that the application lacks inventive step. Typical examples of such “non-technical” inventions are claims to implementing computerised business methods. Under the current EPO approach, such claims are considered to relate to patentable subject-matter if they claim or involve something non-abstract, but they are then rejected as lacking inventive step since they do not provide a technical solution to a technical problem.

This approach has not been uniformly adopted by the national courts. Courts in, for example, France and the United Kingdom have rejected such non-technical inventions on the grounds of non-patentable subject-matter rather than lack of inventive step.

Insufficiency of disclosure

Under Article 138(1)(b) EPC, there are grounds for revocation if the patent as granted does not fulfil the corresponding sufficiency requirement for a patent application under **Article 83 EPC**.

The sufficiency requirement is an important means of maintaining the balance between, on the one hand, encouraging or rewarding invention

T 231/97 (Emissionsarme Dispersionsfarben)

T 555/91 (Oxygen enrichment/Teijin)

T 677/91 (Mass selective ejection)

T 812/92 (Formstahl-Walzwerk)

T 645/94 (Treibladungspulver)

T 284/96 (Pigmente/Bayer)

T 626/96 (Commercial success)

T 12/01 (Lactoferrin)

T 252/06 (Flaschendispenser)

T 60/82 (Eichorn Helmut)

T 119/82 (Gelation)

T 939/92 (Triazole)

T 931/95 (Pensions benefits systems)

T 258/03 (Hitachi/Auction method)

T 154/04 (Duns Licensing/estimating sales activity)

Article 83 EPC

Disclosure of the invention

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

and, on the other, ensuring that the invention becomes part of the art for use as a basis for further development and for the free use of the invention after the expiry of the patent. Such is the *quid pro quo* of the patent system. The need for fair protection governs the consideration of both the scope of the claims and the requirement for sufficient disclosure. To this end, the principle has been developed whereby the extent of the monopoly, as defined by the claims, should correspond to the technical contribution of its teaching to the art in question.

Disclosure in the patent

The invention has to be disclosed to the skilled reader in the patent itself, i.e. in the claims, description and drawings (if any). The reader of the patent is deemed to be the person skilled in the art (see above), who is further deemed to possess the relevant common general knowledge (see above). He will make use of such knowledge in reading and interpreting the patent. But information from other documents (extrinsic material) cannot be used to supplement an otherwise insufficient disclosure. Moreover, neither the abstract nor the priority document nor any other document accompanying the application can be used for this purpose. Since no new matter can be added during grant proceedings, insufficiency existing at the filing date in respect of claimed subject-matter cannot be remedied later on. On the other hand, insufficiency can arise as a result of amendments made during grant proceedings.

T 292/85 (Genentech/Polypeptide expression)

T 409/91 (Fuel oils/Exxon)

G 11/91 (Glu-Gln/Celtrix)

The “same invention” has to be based on an enabling specification. Thus, the earlier application has to fulfill the requirement of sufficiency of disclosure.

Patents often contain references to other documents, in particular to applications pending at their filing date. The information in the documents referred to forms part of the original disclosure of the application only if

- it was available to the public at the filing date, or
- it was available to the EPO at the filing date and became available to the public before the publication of the application; and
- the reference is so clear that the skilled reader is able to derive directly and unambiguously the subject-matter of the incorporated document which is intended to form part of the original application.

Article 87 EPC states that a right of priority may be claimed from an earlier application only in respect of the same invention.

Assessment of sufficiency may depend on the claim format. An invention for a product is sufficiently disclosed if the product can be produced. A product claimed for a specific purpose, e.g. a pharmaceutical purpose, is only sufficiently disclosed if it is adapted for this purpose.

T 689/90 (Event detector/Raychem)

T 1497/06 (GPCR/Arena)

Breadth of claims

A critical aspect of the general principle that the protection given should correspond to the contribution made to the art is the allowable breadth of the claims. Usually, the claims generalise the specific embodiments in the description, in particular in the examples. The applicant is permitted to include in the originally filed claims all obvious modifications, equivalents and variants of the subject-matter disclosed, because the skilled person is presumed to be aware of such alternatives. Thus, it is regarded as fair and proportionate to protect the proprietor against the use of such alternatives, taking into account the fact that the applicant is not in a position to describe all possible alternatives at the filing date.

This raises the question as to how many ways of teaching the skilled person how to carry out the invention have to be disclosed. In principle, an invention is sufficiently disclosed if at least one way of carrying out the invention is clearly described. A separate example pursuant to **Rule 42(1)(e) EPC** may be unnecessary if the description, claims and drawings (if any) are detailed enough to provide the skilled person with the necessary information. A single embodiment may thus be sufficient to support even a broad claim. If the invention goes against prevailing technical opinion or is conceptually different from earlier proposals in the art, at least one reproducible example is necessary. However, sufficiency of disclosure requires the skilled person to be able to carry out substantially all the embodiments falling within the ambit of the claims. This requires him to assume that the effect aimed at by the invention may be obtained outside the conditions of a single example. If the invention teaches to apply a known technical method in a specific technical field, and the technical contribution is to be seen in providing the necessary steps, this disclosure cannot be generalised to fields of application for which the necessary steps have not been disclosed.

The skilled person is not expected to look for non-workable embodiments. Rather, it is his task, on the basis of his common general knowledge, to choose, from among given alternatives, those which lead to success. Although it may be possible to find conditions within a claim that do not lead to the desired result, e.g. by using extreme circumstances or correlations, the question to be answered is rather whether or not the skilled person, using the best of his abilities and trying to make the invention work, would, in reality, consider them. Claims defined by ranges are legitimate and allowable if the skilled person is given reasonable areas for which he can find combinations of components, including the end values. This may be a situation in which more than one example is required to illustrate that the invention can be carried out as claimed.

However, the act of finding workable embodiments within a broad claim must not give rise to an undue burden for the skilled person. Whereas a

T 1616/09 (Combination therapy with anti-neoplastic agent and DNA methylation inhibitor/Supergen)

Rule 42(1) EPC

Content of the description

The description shall:

(a) specify the technical field to which the invention relates;

(b) indicate the background art which, as far as is known to the applicant, can be regarded as useful to understand the invention, draw up the European search report and examine the European patent application, and, preferably, cite the documents reflecting such art;

(c) disclose the invention, as claimed, in such terms that the technical problem, even if not expressly stated as such, and its solution can be understood, and state any advantageous effects of the invention with reference to the background art;

(d) briefly describe the figures in the drawings, if any;

(e) describe in detail at least one way of carrying out the invention claimed, using examples where appropriate and referring to the drawings, if any;

(f) indicate explicitly, when it is not obvious from the description or nature of the invention, the way in which the invention is industrially applicable.

Generics v Lundbeck, [2009] RPC (2009) 126 (6): 407–436

T 792/00 (Varied binding proteins/Dyax)

T 1440/07 (Gene expression/Serono)

T 694/92 (Modifying plant cells/Mycogen)

T 973/98 (Mitsubishi Chemical Corporation)

T 43/01 (Akzo Nobel)

reasonable amount of trial and error is permissible, e.g. in an unexplored field, the skilled person has to have at his disposal, either from the information in the specification or on the basis of his common general knowledge, adequate information leading necessarily and directly towards success through the evaluation of possible initial failures. This is not the case if the necessary amount of experimentation amounts to what is in effect a research programme.

Problems may arise if the claims are defined in functional language. In respect of sufficiency of disclosure, functional features are allowable if they give clear instructions on how to reduce them to practice without undue burden. This will be the case if the skilled person knows of several means readily available for executing the function, these means being accessible on the basis of a technical concept fit for generalisation. If this is the case, and if further, as yet unknown, means may become available, the functional definition may comprise as yet unknown embodiments if the person skilled in the art is able to test without undue effort whether possible candidates are suitable for fulfilling the function.

Biological inventions

For inventions involving living matter, it is not always possible to describe the material involved in writing in such a way that it could be obtained or reproduced by a skilled person. Rule 31 EPC, supplementing **Article 83 EPC**, allows an otherwise insufficient disclosure to be made good by the deposit of biological material which is not available to the public and which is not amenable to being described in such a manner as to enable the invention to be carried out.

The formal requirements regarding deposits are set out in **Rules 31 to 33 EPC**.

The deposit of biological material is not a formal requirement of the application, but a substantive requirement of sufficiency of disclosure. Therefore, a deposit of biological material indicated in the description is not necessary if this material is permanently available to the public from reliable sources. Nor is a deposit necessary if the indicated material it is not necessary for carrying out the invention because the description contains sufficient information on how to obtain other suitable material for this purpose. If the deposit is necessary, a claimed priority is only valid if the deposit was made up to the priority date.

T 123/06 (Vapour dispensing device/
Reckitt Benckiser)

T 243/91 (Screw conveyor)

T 435/91 (Detergents/Unilever)

BGH, GRUR 2013, 1210 – “*Dipeptidyl-
Peptidase-Inhibitoren*”

Article 83 EPC

Disclosure of the invention

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

Rules 31 to 33 EPC

- The deposit must have been made not later than the filing date of the application with a recognised depository on the same terms as laid down in the Budapest Treaty concerning the Deposit of Micro-organisms.
- The application as filed must give such relevant information as is available to the applicant on the characteristics of the biological material.
- The depository institution and the accession number of the material have to be stated in the application; this information has to be submitted at the latest within 16 months from the date of filing or priority.
- The deposited material must be available to the public upon request from the date of publication of the application; the applicant may restrict the access for certain periods to a recognised expert.

Relationship to other requirements: Article 84 EPC

In appropriate cases, the features of a claim may be defined by parameters, i.e. measured values of the properties of a particular subject-matter. Objections to sufficiency of disclosure are often based on the argument that there are different measuring methods or that the measuring method indicated can be applied under different conditions giving rise to different results. Such submissions are not enough to prove insufficiency of disclosure. The fact that an ill-defined parameter allows different ways of measuring, entailing different results, may result in the skilled person not knowing whether he is working within or outside the scope of the claim. While this may be a lack of clarity of the claim, it does not mean that the skilled person cannot reproduce the invention. For establishing insufficiency, it has to be shown that the skilled person, following the instructions in the patent, would choose measuring values which would not allow him reliably to achieve the result aimed at by the invention without undue burden.

Insufficiency of disclosure may be caused by the fact that the application was filed too early, at a stage of development when the expectation of success was still speculative, and the disclosure gives only vague guidance for performing the invention. In some cases of this type, the Boards of Appeal have applied the patentability requirement for industrial application under **Article 57 EPC**, concluding that providing a new substance (e.g. a peptide) does not necessarily mean that the requirement of industrial application is fulfilled, unless there is some profitable use to which the substance can be put. The boards clarified this by stating that a patentable invention has to define in technical terms a purpose and how it can be used in industrial practice to solve a problem. There has to be a real, as opposed to a purely theoretical, possibility of exploitation. Providing a new substance for further research in the mere hope of identifying some useful application is not sufficient.

A substantiated objection to sufficiency of disclosure must be based on serious doubts derived from verifiable facts. Where the parties make contradictory but unsubstantiated assertions concerning facts relevant for establishing patentability and the EPO is not in a position to establish the facts of its own motion, the benefit of the doubt is given to the patent proprietor. The strength of the presumption that the invention is sufficiently disclosed depends on the nature and detail of the information given in the specification.

T 418/89 (Monoclonal antibody/ORTHO)

G 2/93 (Hepatitis A virus/United States of America II)

T 361/87 (Micro-organisms/Nabisco)

Article 84 EPC Claims

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

T 396/02 (Hair conditioning composition)

T 1052/98 (Gene switch/Syngenta)

Article 57 EPC Industrial application

An invention shall be considered as susceptible of industrial application if it can be made or used in any kind of industry, including agriculture

T 870/04 (BDP1 Phosphatase/MAX-PLANCK)

T 898/05 (Hematopoietic receptor/Zymogenetics)

T 19/90 (Onco-mouse/Harvard)

T 72/04 (Pulp heating/Kvaerner)