Part G

Patentability

Contents

Chapter I – Patentability

1. Basic requirements

There are four basic requirements for patentability: *Art. 52(1)*

(i) there must be an "invention", belonging to any field of technology (see G-II);

(ii) the invention must be "susceptible of industrial application" (see G-III);

(iii) the invention must be "new" (see G-IV to VI); and

(iv) the invention must involve an "inventive step" (see G-VII).

2. Further requirements

In addition to these four basic requirements, the examiner should be aware of the following two requirements that are implicitly contained in the EPC:

(i) the invention must be such that it can be carried out by a person skilled in the art (after proper instruction by the application); this follows from Art. 83. Instances where the invention fails to satisfy this requirement are given in F-III, 3; and *Art. 83*

(ii) the invention must be of "technical character" to the extent that it must relate to a technical field (Rule 42(1)(a)), must be concerned with a technical problem (Rule 42(1)(c)), and must have technical features in terms of which the matter for which protection is sought can be defined in the claim (Rule 43(1)) (see F-IV, 2.1). *Rule 42(1)(a) and (c)* *Rule 43(1)*

3. Technical progress, advantageous effects

The EPC does not require explicitly or implicitly that an invention, to be patentable, must entail some technical progress or even any useful effect. Nevertheless, advantageous effects, if any, with respect to the state of the art should be stated in the description (Rule 42(1)(c)), and any such effects are often important in determining "inventive step" (see G-VII, 5).

Chapter II – Inventions

1. General remarks

Art. 52(2) and (3)

The EPC does not define what is meant by "invention", but Art. 52(2) contains a non-exhaustive list of things which are not regarded as inventions. It will be noted that the items on this list are all either abstract (e.g. discoveries or scientific theories) and/or non-technical (e.g. aesthetic creations or presentations of information). In contrast to this, an "invention" within the meaning of Art. 52(1) must be of both a concrete and a technical character (see G-I, 2(ii)). It may be in any field of technology.

2. Examination practice

In considering whether the subject-matter of an application is an invention within the meaning of Art. 52(1), there are two general points the examiner must bear in mind. Firstly, any exclusion from patentability under Art. 52(2) applies only to the extent to which the application relates to the excluded subject-matter as such (Art. 52(3)). Secondly, the subject-matter of the claim should be considered as a whole, in order to decide whether the claimed subject-matter has a technical character. If it does not, there is no invention within the meaning of Art. 52(1).

It must also be borne in mind that the basic test of whether there is an invention within the meaning of Art. 52(1) is separate and distinct from the questions whether the subject-matter is susceptible of industrial application, is new and involves an inventive step. Technical character should be assessed without regard to the prior art (see T 1173/97, confirmed by G 3/08).

It should be noted that the assessment of technical character should not stop as soon as it has been established that the claim as a whole is not excluded from patentability under Art. 52(2) and (3). In claims comprising technical and non-technical aspects, each aspect has to be evaluated to see if it contributes to the technical character of the claimed subject-matter, since this is relevant for assessing inventive step (see G-VII, 5.4).

Where it is found that the claims relate in part to excluded subject-matter, this may have led to the issuing of a partial European or supplementary European search report under Rule 63 (see B-VIII, 1, 3.1 and 3.2). In such cases, in the absence of appropriate amendment and/or convincing arguments provided by the applicant in his response to the invitation under Rule 63(1) (see B-VIII, 3.2) or to the search opinion under Rule 70a (see B-XI,8), an objection under Rule 63(3) will also arise (see H-II, 5).

3. List of exclusions

The items on the list in Art. 52(2) will now be dealt with in turn, and further examples will be given in order better to clarify the distinction

between what is patentable in the sense of not being excluded from patentability under Art. 52(2) and (3) and what is not.

3.1 Discoveries

Art. 52(2)(a) If a new property of a known material or article is found out, that is mere discovery and unpatentable because discovery as such has no technical effect and is therefore not an invention within the meaning of Art. 52(1). If, however, that property is put to practical use, then this constitutes an invention which may be patentable. For example, the discovery that a particular known material is able to withstand mechanical shock would not be patentable, but a railway sleeper made from that material could well be patentable. To find a previously unrecognised substance occurring in nature is also mere discovery and therefore unpatentable. However, if a substance found in nature can be shown to produce a technical effect, it may be patentable. An example of such a case is that of a substance occurring in nature which is found to have an antibiotic effect. In addition, if a microorganism is discovered to exist in nature and to produce an antibiotic, the microorganism itself may also be patentable as one aspect of the invention. Similarly, a gene which is discovered to exist in nature may be patentable if a technical effect is revealed, e.g. its use in making a certain polypeptide or in gene therapy.

For further specific issues concerning biotechnological inventions see G-II, 5, 5.3 to 5.5, and G-III, 4.

3.2 Scientific theories

Art. 52(2)(a) These are a more generalised form of discoveries, and the same principle as set out in G-II, 3.1 applies. For example, the physical theory of semiconductivity would not be patentable. However, new semiconductor devices and processes for manufacturing these may be patentable.

3.3 Mathematical methods

Art. 52(2)(a) These are a particular example of the principle that purely abstract or intellectual methods are not patentable. For example, an abstract shortcut method of division would be excluded from patentability by Art. 52(2)(a) and (3). However, a calculating machine constructed to operate accordingly (e.g. by executing a program designed to carry out the method) would not be excluded. Electrical filters designed according to a particular mathematical method would also not be excluded.

Furthermore, a method for analysing the cyclical behaviour of a curve relating two parameters, which are not further specified, to one another is a mathematical method as such, excluded from patentability by Art. 52(2)(a) and (3), unless it uses technical means, for example, if it is computer-implemented.

A claim directed to a technical process in which a mathematical method is used, thus being restricted to a particular application of the

mathematical method in a technical field, does not seek protection for the mathematical method as such. For instance, a method of encoding audio information in a communication system may aim to reduce distortion induced by channel noise. Although the idea underlying such a method may be considered to reside in a mathematical method, the encoding method as a whole is not a mathematical method as such, and hence is not excluded from patentability by Art. 52(2)(a) and (3). Similarly, a method of encrypting/decrypting or signing electronic communications may be regarded as a technical method, even if it is essentially based on a mathematical method (see T 1326/06).

A procedural step (e.g. a mathematical algorithm) may contribute to the technical character of a claimed method only if it serves an adequately defined technical purpose of the method. In particular, specific technical applications of computer-implemented simulation methods, even if involving mathematical formulae, are to be regarded as modern technical methods which form an essential part of the fabrication process. Such simulation methods cannot be denied a technical effect merely on the ground that they do not yet incorporate the physical end product. However, the meta-specification of an undefined technical purpose (for example, the simulation of a "technical system"), could not be considered adequate (T 1227/05).

In a mathematical method for processing data, although defining the origin of the data records, i.e. what the data represents, may imply technical aspects, it does not necessarily confer technical character upon the method. For example, in a mathematical method for classifying data records, the classification algorithm would not derive a technical character from specifying that the data records are assembled from events in a telecommunications network if the classification is not performed for a technical purpose. What is also decisive is whether a technical effect is achieved by the functional nature of the data irrespective of its cognitive content (see T 1194/97, T 1161/04). For example, a mathematical method for processing data representing an image stored as an electric signal by a computer-implemented method and providing as its result a certain change in the image (e.g. restoring the image if it is distorted) is considered as being used in a technical process (T 208/84 and T 1161/04).

The increased speed or efficiency of a method based on improved algorithms is not sufficient on its own to establish a technical character of the method (see T 1227/05). Characteristics such as speed and efficiency are inherent in both technical and non-technical methods. For example, if a sequence of auction steps leads to price determination more quickly than some other auction method, that does not necessarily imply that the auction steps contribute to the technical character of the method (see T 258/03).

3.4 Aesthetic creations

Art. 52(2)(b)

Subject-matter relating to aesthetic creations will usually have both technical aspects, e.g. a 'substrate' such as a canvas or a cloth, and aesthetic aspects, the appreciation of which is essentially subjective, e.g. the form of the image on the canvas or the pattern on the cloth. If technical aspects are present in such an aesthetic creation, it is not an aesthetic creation ‘as such’ and it is not excluded from patentability.

A feature which might not reveal a technical aspect when taken by itself could have a technical character if it brings about a technical effect. For example, the pattern of a tyre tread may actually be a further technical feature of the tyre if, for example, it provides improved channelling of water. On the contrary, this would not be the case when a particular colour of the sidewall of the tyre serves only an aesthetic purpose.

The aesthetic effect itself is not patentable, neither in a product nor in a process claim.

For example, features relating solely to the aesthetic or artistic effect of the information content of a book, or to its layout or letterfont, would not be considered as technical features. Neither would features such as the aesthetic effect of the subject of a painting or the arrangement of its colours or its artistic (e.g. Impressionist) style be technical. Nevertheless, if an aesthetic effect is obtained by a technical structure or other technical means, although the aesthetic effect itself is not of a technical character, the means of obtaining it may be. For example, a fabric may be provided with an attractive appearance by means of a layered structure not previously used for this purpose, in which case a fabric incorporating such structure might be patentable.

Similarly, a book defined by a technical feature of the binding or pasting of the back is not excluded from patentability under Art. 52(2) and (3), even though it has an aesthetic effect too. A painting defined by the kind of cloth, or by the dyes or binders used, is likewise not excluded.

A technical process, even if it is used to produce an aesthetic creation (such as a cut diamond), is nevertheless a technical process which is not excluded from patentability. Similarly, a printing technique for a book resulting in a particular layout with aesthetic effect is not excluded, and nor is the book as a product of that process. Again, a substance or composition defined by technical features serving to produce a special effect with regard to scent or flavour, e.g. to maintain a scent or flavour for a prolonged period or to accentuate it, is not excluded.

Art. 52(2)(c)

3.5 Schemes, rules and methods for performing mental acts, playing games or doing business

These are further examples of items of an abstract or intellectual character. In particular, a scheme for learning a language, a method of

solving crossword puzzles, a game (as an abstract entity defined by its rules), modelling information or a scheme for organising a commercial operation would not be patentable. A method of doing business is excluded from patentability even where it implies the possibility of making use of unspecified technical means or has practical utility (see T 388/04). Another example is that of a method for designing a nuclear core loading arrangement, which neither specifies the use of means or measures of a technical nature nor includes the provision of a physical entity as the resulting product (e.g. a reactor core loaded according to the given design). This method may exclusively be carried out mentally and thus lacks technical character, regardless of the complexity of the method or any technical considerations involved (see T 914/02).

However, if the claimed subject-matter specifies an apparatus or a technical process for carrying out at least some part of the scheme, that scheme and the apparatus or process have to be examined as a whole. In particular, if the claim specifies computers, computer networks or other conventional programmable apparatus, a program therefor, or a storage medium carrying the program, for executing at least some steps of a scheme, it may comprise a mix of technical and non-technical features, with the technical features directed to a computer or a comparable programmed device. In these cases, the claim is to be examined as a "computer-implemented invention" (see below).

3.6 Programs for computers

Art. 52(2)(c)

Inventions involving programs for computers can be protected in different forms of a "computer-implemented invention", an expression intended to cover claims which involve computers, computer networks or other programmable apparatus whereby *prima facie* one or more of the features of the claimed invention are realised by means of a program or programs. Such claims directed at computer-implemented inventions may e.g. take the form of a method of operating said apparatus, the apparatus set up to execute the method, or, following T 1173/97, the computer program itself as well as the physical media carrying the program (see T 424/03), i.e. computer program product claims, such as "data carrier", "storage medium", "computer readable medium" or "signal".

The category of a claim directed to a computer-implemented method is distinguished from that of a claim directed to a computer program corresponding to that method (T 424/03 and G 3/08). Such claims therefore have to be examined separately.

Technical character should be assessed without regard to the prior art (see T 1173/97, confirmed by G 3/08). Features of the computer program itself (see T 1173/97) as well as the presence of a device defined in the claim (see T 424/03 and T 258/03) may potentially lend technical character to the claimed subject-matter as explained below. In particular in embedded systems, a data processing operation

implemented by means of a computer program can equally be implemented by means of special circuits (e.g. by field-programmable gate arrays).

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 included among the items listed in Art. 52(2), if the claimed subject-matter has a technical character it is not excluded from patentability by the provisions of Art. 52(2) and (3).

A computer program claimed by itself is not excluded from patentability if it is capable of bringing about, when running on or loaded into a computer, a further technical effect going beyond the "normal" physical interactions between the program (software) and the computer (hardware) on which it is run (T 1173/97 and G 3/08). The normal physical effects of the execution of a program, e.g. electrical currents, are not in themselves sufficient to lend a computer program technical character, and a further technical effect is needed. The further technical effect may be known in the prior art.

Likewise, although it may be said that all computer programming involves technical considerations since it is concerned with defining a method which can be carried out by a machine, that in itself is not enough to demonstrate that the program which results from the programming has technical character; the programmer must have had technical considerations beyond "merely" finding a computer algorithm to carry out some procedure (G 3/08).

A further technical effect which lends technical character to a computer program may be found e.g. in the control of an industrial process 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 computer resources required or the rate of data transfer in a communication link. A computer program implementing a mathematical method that itself makes a technical contribution (see G-II, 3.3) would also be considered to be capable of bringing about a further technical effect when it is run on a computer.

A patent may be granted on one of the different forms of a computer program product claim if all the requirements of the EPC are met; see in particular Art. 84, 83, 54 and 56, and G-III, 3 below. Such claims should not contain program listings, but should define all the features which assure patentability of the process which the program is intended to carry out when it is run (see F-IV, 4.5.2, last sentence). Short excerpts from programs might be accepted in the description (see F-II, 4.12).

Whether a computer program can contribute to the technical character of the claimed subject-matter is frequently an issue separate and distinct from the technical character of the hardware components

which may be defined in order to execute the computer program. When a computer program produces a further technical effect (T 1173/97), it is by itself considered technical and not excluded. In contrast, any claimed subject-matter defining or using technical means is an invention within the meaning of Art. 52(1) (see T 424/03 and T 258/03, and confirmed in G 3/08). This applies even if the technical means are commonly known; for example, the inclusion of a computer, a computer network, a readable medium carrying a program, etc. in a claim lends technical character to the claimed subject-matter.

If claimed subject-matter relating to a computer program does not have a technical character, it should be rejected under Art. 52(2) and (3). If the subject-matter passes this test for technicality, the examiner should then proceed to the questions of novelty and inventive step (see G-VI and VII).

3.7 Presentations of information

Art. 52(2)(d)

A feature relating to a presentation of information defined solely by the content of the information does not have a technical character. This applies whether the feature is claimed as a presentation of the information *per se* (e.g. by acoustical signals, spoken words, visual displays, books defined by their subject, gramophone records defined by the musical piece recorded, traffic signs defined by the warning thereon) or as relating to processes and apparatus for presenting information (e.g. features of indicators or recorders defined solely by the information indicated or recorded would not be technical features).

A feature which relates to the manner in which cognitive content is conveyed to the user on a screen normally does not contribute to a technical solution to a technical problem. An exception would be if the arrangement or manner of presentation can be shown to have a credible technical effect (T 1741/08, T 1143/06).

Examples in which such a technical feature may be present are: a telegraph apparatus or communication system using a particular code to represent the characters (e.g. pulse code modulation); a measuring instrument designed to produce a particular form of graph for representing the measured information; a gramophone record having a particular groove form to allow stereo recordings; a computer data structure (see T 1194/97) defined in terms which inherently comprise the technical features of the program which operates on said data structure (assuming the program itself, in the particular case, to be patentable); and a diapositive with a soundtrack arranged at the side of it.

When assessing the exclusion from patentability under Art. 52(2), the subject-matter of the claim has to be considered as a whole (G-II, 2). For example, a claim directed to a product (e.g. a bleaching composition) and to instructions for use of the product, wherein the instructions have no technical effect on the product, is not excluded since the claim has a technical meaning and defines the technical

features necessary for the definition of the claimed subject-matter, i.e. a product comprising a composition of matter (T 553/02).

When deciding if a feature relating to the presentation of information is technical or not, what has to be considered is whether or not it contributes to solving a technical problem. The fact that mental activities are involved does not on its own render the subject-matter non-technical (T 643/00). However, a feature that solely addresses a user's subjective preferences does not solve a technical problem (T 1567/05). In the context of automated systems, in particular computers, giving visual indications of an automatically detected event occurring in the system itself as a prompt for human interaction with the system, e.g. to avoid technical malfunctions, is usually regarded as making a technical contribution. On the other hand, a visual indication aimed exclusively at the mental activities of the viewer, in particular at preparing the relevant data for a non-technical decision-making process by the user as the final addressee, is usually not regarded as making a technical contribution (T 756/06). Presenting the state of some non-technical application executed on a computer is normally not considered to be technical, either.

3.7.1 User interfaces

Features concerning the graphic design of user interfaces do not have a technical effect, because their design is not based on technical considerations, but on general intellectual considerations as to which design is particularly appealing to a user.

For example, the colour, shape, size, layout, arrangement of items on the screen or the information content of a message displayed is usually not a technical aspect of a graphical user interface.

However, the examiner must check whether these features contribute to achieving a particular technical effect if, e.g.:

– they are combined with steps of or means for interacting with a user or

– they concern technical information (e.g. internal machine states).

3.7.2 Data retrieval, formats and structures

A computer-implemented data structure (see T 1194/97) or a computer-implemented data format embodied on a medium or as an electromagnetic carrier wave has technical character (because the storage medium is a technical artefact) and thus is an invention in the sense of Art. 52(1). Such data structures or formats may comprise a mixture of cognitive content and functional data.

Technical effects associated with data structures or formats when using said data structure or format during the operation of a computer system could give rise to, for example: efficient data processing,

efficient data storage, enhanced security. On the other hand, features merely describing data collections on a logical level do not provide a technical effect, even if such a description might involve a particular modelling of the described data.

A data structure in itself is merely a static memory configuration. Therefore, when a data structure is claimed by itself, a technical effect cannot be directly identified since there is no method being carried out. Furthermore, a claimed data structure can potentially be used in combination with different algorithms or methods for completely different purposes.

For these reasons the examiner should check whether the data structure as claimed inherently comprises the technical features of the system or the steps of a corresponding method which forms the basis of the technical effect.

4. Exceptions to patentability

4.1 Matter contrary to "*ordre public*" or morality

Any invention the commercial exploitation of which would be contrary to "*ordre public*" or morality is specifically excluded from patentability. The purpose of this is to deny protection to inventions likely to induce riot or public disorder, or to lead to criminal or other generally offensive behaviour (see also F-II, 7.2). Anti-personnel mines are an obvious example. This provision is likely to be invoked only in rare and extreme cases. A fair test to apply is to consider whether it is probable that the public in general would regard the invention as so abhorrent that the grant of patent rights would be inconceivable. If it is clear that this is the case, objection should be raised under Art. 53(a); otherwise not. The mere possibility of abuse of an invention is not sufficient to deny patent protection pursuant to Art. 53(a) EPC if the invention can also be exploited in a way which does not and would not infringe "*ordre public*" and morality (see T 866/01). If difficult legal questions arise in this context, then refer to C-VIII, 7. *Art. 53(a)*

Where it is found that the claims relate in part to such excluded subject-matter, this may have led to the issuing of a partial European or supplementary European search report under Rule 63 (see B-VIII, 1, 3.1 and 3.2). In such cases, in the absence of appropriate amendment and/or convincing arguments provided by the applicant in his response to the invitation under Rule 63(1) (see B-VIII, 3.2) or to the search opinion under Rule 70a (see B-XI, 8), an objection under Rule 63(3) will also arise (see H-II, 5).

4.1.1 Prohibited matter

Exploitation is not to be deemed to be contrary to "*ordre public*" or morality merely because it is prohibited by law or regulation in some or all of the Contracting States. One reason for this is that a product could still be manufactured under a European patent for export to States in which its use is not prohibited. *Art. 53(a)*

4.1.2 Offensive and non-offensive use

Special attention should be paid to applications in which the invention has both an offensive and a non-offensive use, e.g. a process for breaking open locked safes, the use by a burglar being offensive but the use by a locksmith in the case of emergency non-offensive. In such a case, no objection arises under Art. 53(a). Similarly, if a claimed invention defines a copying machine with features resulting in an improved precision of reproduction and an embodiment of this apparatus could comprise further features (not claimed but apparent to the skilled person) the only purpose of which would be that it should also allow reproduction of security strips in banknotes strikingly similar to those in genuine banknotes, the claimed apparatus would cover an embodiment for producing counterfeit money which could be considered to fall under Art. 53(a). There is, however, no reason to consider the copying machine as claimed to be excluded from patentability, since its improved properties could be used for many acceptable purposes (see G 1/98, Reasons 3.3.3). However, if the application contains an explicit reference to a use which is contrary to "*ordre public*" or morality, deletion of this reference should be required under the terms of Rule 48(1)(a).

4.1.3 Economic effects

The EPO has not been vested with the task of taking into account the economic effects of the grant of patents in specific areas of technology and of restricting the field of patentable subject-matter accordingly (see G 1/98 Reasons 3.9, and T 1213/05). The standard to apply for an exception under Art. 53(a) is whether the commercial exploitation of the invention is contrary to "*ordre public*" or morality.

4.2 Surgery, therapy and diagnostic methods

Art. 53(c)

European patents are not to be granted in respect of "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." Hence, patents may be obtained for surgical, therapeutic or diagnostic instruments or apparatuses for use in such methods. The manufacture of prostheses or artificial limbs could be patentable. For instance, a method of manufacturing insoles in order to correct the posture or a method of manufacturing an artificial limb should be patentable. In both cases, taking the imprint of the footplate or a moulding of the stump on which an artificial limb is fitted is clearly not of a surgical nature and does not require the presence of a medically qualified person. Furthermore, the insoles as well as the artificial limb are manufactured outside the body. However, a method of manufacturing an endoprosthesis outside the body, but requiring a surgical step to be carried out for taking measurements, would be excluded from patentability under Art. 53(c) (see T 1005/98).

Art. 54(4)

Patents may be obtained for **new** products, particularly substances or compositions, for use in these methods of treatment or diagnosis.

According to Art. 54(4), where the substance or composition is known, it may only be patented for use in these methods if the known substance or composition was not previously disclosed for use in surgery, therapy or diagnostic methods practised on the human or animal body ("**first medical use**"). A claim to a known substance or composition for the first use in surgical, therapeutic and/or diagnostic methods should be in a form such as: "Substance or composition X" followed by the indication of the use, for instance "... for use as a medicament" or "... for use in therapy/diagnostics/surgery". If the known substance or composition was previously disclosed for use in surgery, therapy or diagnostic methods practised on the human or animal body ("**further medical use**"), the claim should be in the form: "Substance or composition X" followed by the indication of the **specific** therapeutical/diagnostic/surgical use, for instance, "... for use in treating disease Y" (see G-VI, 7.1).

4.2.1 Limitations of exception under Art. 53(c)

Art. 53(c)

It should be noted that the exceptions under Art. 53(c) are confined to methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body. It follows that other methods of treatment of live human beings or animals (e.g. treatment of a sheep in order to promote growth, to improve the quality of mutton or to increase the yield of wool) or other methods of measuring or recording characteristics of the human or animal body are patentable, provided that (as would probably be the case) such methods are of a technical and not essentially biological character (see G-II, 5.4). For example, an application containing claims directed to the purely cosmetic treatment of a human by administration of a chemical product is considered as being patentable (see T 144/83). A cosmetic treatment involving surgery or therapy would, however, not be patentable (see below).

To be excluded from patentability, a treatment or diagnostic method must actually be carried out on the living human or animal body. A treatment of or diagnostic method practised on a dead human or animal body would therefore not be excluded from patentability by virtue of Art. 53(c). Treatment of body tissues or fluids after they have been removed from the human or animal body, or diagnostic methods applied thereon, are not excluded from patentability insofar as these tissues or fluids are not returned to the same body. Thus the treatment of blood for storage in a blood bank or diagnostic testing of blood samples is not excluded, whereas a treatment of blood by dialysis with the blood being returned to the same body would be excluded.

Regarding methods which are carried out on or in relation to the living human or animal body, it should be borne in mind that the intention of Art. 53(c) is only to free from restraint non-commercial and non-industrial medical and veterinary activities. Interpretation of the provision should avoid the exceptions from going beyond their proper limits (see G 5/83, G 1/04, and G 1/07).

Whether or not a method is excluded from patentability under Art. 53(c) cannot depend on the person carrying it out (see G 1/04 and G 1/07, Reasons 3.4.1).

However, in contrast to the subject-matter referred to in Art. 52(2) and (3) which is only excluded from patentability if claimed as such, a method claim is not allowable under Art. 53(c) if it includes at least one feature defining a physical activity or action that constitutes a method step for treatment of the human or animal body by surgery or therapy. In that case, whether or not the claim includes or consists of features directed to a technical operation performed on a technical object is legally irrelevant to the application of Art. 53(c) (see G 1/07, Reasons 3.2.5).

4.2.1.1 Surgery

The meaning of the term "treatment by surgery" is not to be interpreted as being confined to surgical methods pursuing a therapeutic purpose (see G 1/07, Reasons 3.3.10). Accordingly, the term "surgery" defines the nature of the treatment rather than its purpose. Thus, for example, a method of treatment by surgery for cosmetic purposes or for embryo transfer is excluded from patentability, as well as surgical treatment for therapeutic purposes. The term "treatments by surgery" further covers interventions performed on the structure of an organism by conservative ("closed, non-invasive") procedures such as repositioning or by operative (invasive) procedures using instruments.

Whether a claimed method is to be considered as surgical treatment excluded from patentability under Art. 53(c) should be assessed on a case-by-case basis, taking the individual merits of each case into account. The aim of Art. 53(c) is that medical and veterinary practitioners should be free to use their skills and knowledge of the best available treatments to achieve the utmost benefit for their patients uninhibited by any worry that some treatment might be covered by a patent (see G 1/07, Reasons 3.3.6).

Thus, any definition of the term "treatment by surgery" must cover the kind of interventions which constitute the core of the medical profession's activities i.e. the kind of interventions for which their members are specifically trained and for which they assume a particular responsibility (G 1/07, Reasons 3.4.2.3).

The exclusion applies to substantial physical interventions on the body which require professional medical expertise to be carried out and which entail a substantial health risk even when carried out with the required professional care and expertise. The health risk must be associated with the mode of administration and not solely with the agent as such (G 1/07, Reasons 3.4.2.3). Examples of excluded treatments by surgery are the injection of a contrast agent into the heart, catheterisation and endoscopy.

Invasive techniques of a routine character which are performed on uncritical body parts and are generally carried out in a non-medical, commercial environment, are not excluded from patentability, e.g. tattooing, piercing, hair removal by optical radiation and micro-abrasion of the skin.

Similar considerations apply to routine interventions in the medical field. Thus, uncritical methods involving only a minor intervention and no substantial health risks, when carried out with the required care and skill, do not fall under the scope of Art. 53(c). This narrower understanding of the exclusion still protects the medical profession from the concerns indicated above.

The required medical expertise and the health risk involved may however not be the only criteria which may be used to determine that a claimed method actually constitutes "treatment by surgery" within the meaning of Art. 53(c). Other criteria, such as the degree of invasiveness or the complexity of the operation performed, could also determine that a physical intervention on the human or animal body constitutes such treatment (see G 1/07, Reasons 3.4.2.4).

The exclusion under Art. 53(c) applies to multi-step methods which comprise or encompass at least one therapeutic or surgical step, as defined in the previous paragraph. The non-patentable subject-matter must be removed from the scope of the claim. This may be done either by means of a disclaimer or by omitting the surgical step from the wording of the claim. The overall patentability of the amended claim will however depend on its compliance with the other requirements of the EPC, which should be assessed on a case-by-case basis.

Finally, when interpreting the scope of the exclusion under Art. 53(c), no distinction is to be made between human beings and animals.

4.2.1.2 Therapy

Therapy implies the curing of a disease or malfunction of the body and covers prophylactic treatment, e.g. immunisation against a certain disease (see T 19/86) or the removal of plaque (see T 290/86). A method for therapeutic purposes concerning the functioning of an apparatus associated with a living human or animal body is not excluded from patentability if no functional relationship exists between the steps related to the apparatus and the therapeutic effect of the apparatus on the body (see T 245/87).

As clinical trials have a therapeutic aspect for the human subjects undergoing them, an objection under Art. 53(c) should be raised if a claim includes a step relating to a method of treatment of the human body by therapy (see G-II, 4.2.2).

4.2.1.3 Diagnostic methods

Diagnostic methods likewise do not cover all methods related to diagnosis. To determine whether a claim is directed to a diagnostic

method within the meaning of Art. 53(c), it must first be established whether all of the necessary phases are included in the claim (G 1/04).

The claim must include method steps relating to **all** of the following phases:

(i) the **examination phase,** involving the collection of data,

(ii) the **comparison** of these data with standard values,

(iii) the **finding of any significant deviation**, i.e. a symptom, during the comparison,

(iv) the attribution of the deviation to a particular clinical picture, i.e. the deductive medical or veterinary **decision phase** (diagnosis for curative purposes *stricto sensu*).

If features pertaining to any of these phases are missing and are essential for the definition of the invention, those features are to be included in the independent claim (see Example 9 in Annex II of F-IV). Due account should be taken of steps which may be considered to be implicit: for example, steps relating to the comparison of data with standard values (phase (ii)) may imply the finding of a significant deviation (phase (iii) - see T 1197/02). The deductive medical or veterinary decision phase (iv), i.e. the "diagnosis for curative purposes *stricto sensu*", is the determination of the nature of a medical or veterinary medicinal condition intended to identify or uncover a pathology; the identification of the underlying disease is not required (see T 125/02).

It is then necessary to establish which of the method steps have **technical character**. The final phase (iv), for example, is normally a purely intellectual exercise (unless a device capable of reaching the diagnostic conclusions can be used) and therefore not technical in character.

In order to fulfil the "practised on the human or animal body" criterion, **each of the preceding technical method steps relating to phases (i) to (iii) must be performed on a human or animal body**. So, for each technical method step, it must be ascertained whether an interaction with the human or animal body takes place. The type or intensity of the interaction is not decisive: this criterion is fulfilled if the performance of the technical method step in question necessitates the presence of the body. Direct physical contact with the body is not required.

It is noted that a medical or veterinary practitioner does not have to be involved, either by being present or by bearing the overall responsibility, in the procedure.

If all of the above criteria are satisfied, then the claim defines a diagnostic method practised on the human or animal body, and an objection will be raised under Art. 53(c).

Accordingly, methods for merely obtaining information (data, physical quantities) from the living human or animal body (e.g. X-ray investigations, MRI studies, and blood pressure measurements) are not excluded from patentability under Art. 53(c).

4.2.2 Methods for screening potential medicaments and clinical trials

Art. 53(a)

The scope of protection of a claim directed to a standard compound screening test carried out on "animals" encompasses preclinical tests carried out with libraries of compounds on human beings. In order for such a claim to be allowable under Art. 53(a), the use of human beings as "test animals" should be clearly excluded from the scope of the claim, e.g. by means of a disclaimer.

In some infrequent cases, a claim may, in the light of the description, be interpreted as exclusively relating to a clinical trial of an experimental medicament carried out on human beings. Such trials are ethically acceptable, since they are performed under strictly controlled conditions and with informed consent of the patient concerned. Therefore, no objection under Art. 53(a) should be raised (see however G-II, 4.2.1.2).

5. Exclusions and exceptions for biotechnological inventions

5.1 General remarks and definitions

Rule 26(2) and (3)

"Biotechnological inventions" are inventions which concern a product consisting of or containing biological material or a process by means of which biological material is produced, processed or used. "Biological material" means any material containing genetic information and capable of reproducing itself or being reproduced in a biological system.

5.2 Patentable biotechnological inventions

Rule 27
Rule 26(1)

In principle, biotechnological inventions are patentable under the EPC. For European patent applications and patents concerning biotechnological inventions, the relevant provisions of the EPC are to be applied and interpreted in accordance with the provisions of Rules 26 to 29. European Union Directive 98/44/EC of 6 July 1998 on the legal protection of biotechnological inventions (OJ EPO 1999, 101) is to be used as a supplementary means of interpretation. In particular the recitals (abbreviated as rec.) preceding the provisions of the Directive are also to be taken into account.

Biotechnological inventions are also patentable if they concern an item on the following non-exhaustive list:

Rule 27(a)

(i) Biological material which is **isolated** from its natural environment or produced by means of a technical process even if it previously occurred in nature

Hence, biological material may be considered patentable even if it already occurs in nature (see also G-II, 3.1).

Rule 29(1) and (2)

Although the human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions (see G-II, 5.3), an element isolated from the human body or otherwise produced by means of a technical process, which is susceptible of industrial application, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element. Such an element is not a priori excluded from patentability since it is, for example, the result of technical processes used to identify, purify and classify it and to produce it outside the human body, techniques which human beings alone are capable of putting into practice and which nature is incapable of accomplishing itself (EU Dir. 98/44/EC, rec. 21).

Rule 29(3)

The examination of a patent application or a patent for gene sequences or partial sequences should be subject to the same criteria of patentability as in all other areas of technology (EU Dir. 98/44/EC, rec. 22). The industrial application of a sequence or partial sequence must be disclosed in the patent application as filed (see G-III, 4);

Rule 27(b)

(ii) Plants or animals if the technical feasibility of the invention is not confined to a particular plant or animal variety

Inventions which concern plants or animals are patentable provided that the application of the invention is not technically confined to a single plant or animal variety (EU Dir. 98/44/EC, rec. 29).

A claim wherein specific plant varieties are not individually claimed is not excluded from patentability under Art. 53(b) even though it may embrace plant varieties (see G 1/98, and G-II, 5.4).

The subject-matter of a claim covering but not identifying plant varieties is not a claim to a variety or varieties (see G 1/98, Reasons 3.8). In the absence of the identification of a specific plant variety in a product claim, the subject-matter of the claimed invention is neither limited nor directed to a variety or varieties

within the meaning of Art. 53(b) (G 1/98, Reasons 3.1 and 3.10); or

(iii) A microbiological or other technical process, or a product obtained by means of such a process other than a plant or animal variety *Rule 27(c)*

"Microbiological process" means any process involving or performed upon or resulting in microbiological material. *Rule 26(6)*

5.3 List of exceptions (Rule 28)

In the area of biotechnological inventions, the following list of exceptions to patentability under Art. 53(a) is laid down in Rule 28. The list is illustrative and non-exhaustive and is to be seen as giving concrete form to the concept of "*ordre public*" and "morality" in this technical field.

Under Art. 53(a), in conjunction with Rule 28, European patents are not to be granted in respect of biotechnological inventions which concern: *Rule 28*

(i) Processes for cloning human beings *Rule 28(a)*

For the purpose of this exception, a process for the cloning of human beings may be defined as any process, including techniques of embryo splitting, designed to create a human being with the same nuclear genetic information as another living or deceased human being (EU Dir. 98/44/EC, rec. 41).

(ii) Processes for modifying the germ line genetic identity of human beings *Rule 28(b)*

(iii) Uses of human embryos for industrial or commercial purposes *Rule 28(c)*

A claim directed to a product, which at the filing date of the application could be **exclusively** obtained by a method which necessarily involved the destruction of human embryos from which the said product is derived is excluded from patentability under Rule 28(c), even if said method is not part of the claim (see G 2/06). The point in time at which such destruction takes place is irrelevant.

When examining subject-matter relating to human embryonic stem cells under Art. 53(a) and Rule 28(c), the following has to be taken into account:

(a) the **entire teaching** of the application, not only the claim category and wording, and

(b) the **relevant disclosure in the description** in order to establish whether products such as stem cell cultures are

obtained exclusively by the use, involving the destruction, of a human embryo or not. For this purpose, the disclosure of the description has to be considered in view of the state of the art at the date of filing.

The exclusion of the uses of human embryos for industrial or commercial purposes does not affect inventions for therapeutic or diagnostic purposes which are applied to the human embryo and are useful to it (EU Dir. 98/44/EC, rec. 42).

Rule 28(d) (iv) 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

The substantial medical benefit referred to above includes any benefit in terms of research, prevention, diagnosis or therapy (EU Dir. 98/44/EC, rec. 45).

Rule 29(1) In addition, the human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions (see, however, G-II, 5.2). Such stages in the formation or development of the human body include germ cells (EU Dir. 98/44/EC, rec. 16).

Also excluded from patentability under Art. 53(a) are processes to produce chimeras from germ cells or totipotent cells of humans and animals (EU Dir. 98/44/EC, rec. 38).

5.4 Plant and animal varieties, essentially biological processes for the production of plants or animals

Art. 53(b) The list of exceptions to patentability under Art. 53(b) also includes "plant or animal varieties or essentially biological processes for the production of plants or animals".

5.4.1 Plant varieties

Rule 26(4) *Rule 27(b)* The term "plant variety" is defined in Rule 26(4). A patent is not to be granted if the claimed subject-matter is directed to a specific plant variety or specific plant varieties. However, if the invention concerns plants or animals and if the technical feasibility of the invention is not confined to a particular plant or animal variety, the invention is patentable (see G-II, 5.2).

A claimed plant grouping is not excluded from patentability under Art. 53(b) if it does not meet the definition of a plant variety set out in Rule 26(4). The method of the plant's production, be it by recombinant gene technology or by a classical plant breeding process, is irrelevant for considering this issue (see T 1854/07).

When a claim to a process for the production of a plant variety is examined, Art. 64(2) is not to be taken into consideration (see G 1/98). Hence, a process claim for the production of a plant variety (or plant varieties) is not a priori excluded from patentability merely because the resulting product constitutes or may constitute a plant variety.

5.4.2 Essentially biological processes for the production of plants or animals

Rule 26(5)

A process for the production of plants or animals which is based on the sexual crossing of whole genomes and on the subsequent selection of plants or animals is excluded from patentability as being essentially biological, even if other technical steps relating to the preparation of the plant or animal or its further treatment are present in the claim before or after the crossing and selection steps (see G 1/08 and G 2/07). To take some examples, a method of crossing, inter-breeding, or selectively breeding, say, horses involving merely selecting for breeding and bringing together those animals (or their gametes) having certain characteristics would be essentially biological and therefore unpatentable. This method remains essentially biological and unpatentable even if it contains an additional feature of a technical nature, for example the use of genetic molecular markers to select either parent or progeny. On the other hand, a process involving inserting a gene or trait into a plant by genetic engineering does not rely on recombination of whole genomes and the natural mixing of plant genes, and hence is patentable. A process of treating a plant or animal to improve its properties or yield or to promote or suppress its growth e.g. a method of pruning a tree, would not be an essentially biological process for the production of plants or animals since it is not based on the sexual crossing of whole genomes and subsequent selection of plants or animals; the same applies to a method of treating a plant characterised by the application of a growth-stimulating substance or radiation. The treatment of soil by technical means to suppress or promote the growth of plants is also not excluded from patentability (see also G-II, 4.2.1).

5.5 Microbiological processes

5.5.1 General remarks

Art. 53(b)
Rule 26(6)

As expressly stated in Art. 53(b), second half-sentence, the exception referred to in the first half-sentence does not apply to microbiological processes or the products thereof.

"Microbiological process" means any process involving or performed upon or resulting in microbiological material. Hence, the term "microbiological process" is to be interpreted as covering not only processes performed upon microbiological material or resulting in such, e.g. by genetic engineering, but also processes which as claimed include both microbiological and non-microbiological steps.

Rule 27(c)

The product of a microbiological process may also be patentable *per se* (product claim). Propagation of the microorganism itself is to be

construed as a microbiological process for the purposes of Art. 53(b). Consequently, the microorganism can be protected *per se* as it is a product obtained by a microbiological process (see G-II, 3.1). The term "microorganism" includes bacteria and other generally unicellular organisms with dimensions beneath the limits of vision which can be propagated and manipulated in a laboratory (see T 356/93), including plasmids and viruses and unicellular fungi (including yeasts), algae, protozoa and, moreover, human, animal and plant cells.

On the other hand, product claims for plant or animal varieties cannot be allowed even if the variety is produced by means of a microbiological process (Rule 27(c)). The exception to patentability in Art. 53(b), first half-sentence, applies to plant varieties irrespective of the way in which they are produced. Therefore, plant varieties containing genes introduced into an ancestral plant by recombinant gene technology are excluded from patentability (G 1/98).

5.5.2 Repeatability of results of microbiological processes

Rule 33(1)

In the case of microbiological processes, particular regard should be had to the requirement of repeatability referred to in F-III, 3. As for biological material deposited under the terms of Rule 31, repeatability is assured by the possibility of taking samples (Rule 33(1)), and there is thus no need to indicate another process for the production of the biological material.

Chapter III – Industrial application

1. General remarks

Art. 57

"An invention shall be considered as susceptible of industrial application if it can be made or used in any kind of industry, including agriculture". "Industry" should be understood in its broad sense as including any physical activity of "technical character" (see G-I, 2), i.e. an activity which belongs to the useful or practical arts as distinct from the aesthetic arts; it does not necessarily imply the use of a machine or the manufacture of an article and could cover e.g. a process for dispersing fog or for converting energy from one form to another. Thus, Art. 57 excludes from patentability very few "inventions" which are not already excluded by the list in Art. 52(2) (see F-II, 1). One further class of "invention" which would be excluded, however, would be articles or processes alleged to operate in a manner clearly contrary to well-established physical laws, e.g. a perpetual motion machine. Objection could arise under Art. 57 only insofar as the claim specifies the intended function or purpose of the invention, but if, say, a perpetual motion machine is claimed merely as an article having a particular specified construction then objection should be made under Art. 83 (see F-III, 3).

2. Method of testing

Methods of testing generally should be regarded as inventions susceptible of industrial application and therefore patentable if the test is applicable to the improvement or control of a product, apparatus or process which is itself susceptible of industrial application. In particular, the utilisation of test animals for test purposes in industry, e.g. for testing industrial products (for example for ascertaining the absence of pyrogenetic or allergic effects) or phenomena (for example for determining water or air pollution) would be patentable.

3. Industrial application vs. exclusion under Art. 52(2)

It should be noted that "susceptibility of industrial application" is not a requirement that overrides the restriction of Art. 52(2), e.g. an administrative method of stock control is not patentable, having regard to Art. 52(2)(c), even though it could be applied to the factory store-room for spare parts. On the other hand, although an invention must be "susceptible of industrial application" and the description must indicate, where this is not apparent, the way in which the invention is thus susceptible (see F-II, 4.9), the claims need not necessarily be restricted to the industrial application(s).

4. Sequences and partial sequences of genes

Rule 42(1)(f)
Rule 29(3)

In general it is required that the description of a European patent application should, where this is not self-evident, indicate the way in which the invention is capable of exploitation in industry. The invention claimed must have such a sound and concrete technical basis that the skilled person can recognise that its contribution to the art could lead to practical exploitation in industry (see T 898/05). In relation to

sequences and partial sequences of genes, this general requirement is given specific form in that the industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application. A mere nucleic acid sequence without indication of a function is not a patentable invention (EU Dir. 98/44/EC, rec. 23). In cases where a sequence or partial sequence of a gene is used to produce a protein or a part of a protein, it is necessary to specify which protein or part of a protein is produced and what function this protein or part of a protein performs. Alternatively, when a nucleotide sequence is not used to produce a protein or part of a protein, the function to be indicated could e.g. be that the sequence exhibits a certain transcription promoter activity.

Chapter IV – State of the art

1. General remarks and definition

An invention is "considered to be new if it does not form part of the state of the art". The "state of the art" is defined as "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". The width of this definition should be noted. There are no restrictions whatever as to the geographical location where or the language or manner in which the relevant information was made available to the public; also no age limit is stipulated for the documents or other sources of the information. There are, however, certain specific exclusions (see G-V). However, since the "state of the art" available to the examiner will mainly consist of the documents listed in the search report, this chapter G-IV deals with the question of public availability only in relation to written description (either alone or in combination with an earlier oral description or use). *Art. 54(1) and (2)*

The principles to be applied in determining whether other kinds of prior art (which could be introduced into the proceedings e.g. by a third party under Art. 115) have been made available to the public are set out in G-IV, 7.1 to 7.4.

For the examination of the novelty of claimed subject-matter, see G-VI. *Art. 52(1)*

A written description, i.e. a document, should be regarded as made available to the public if, at the relevant date, it was possible for members of the public to gain knowledge of the content of the document and there was no bar of confidentiality restricting the use or dissemination of such knowledge. For instance, German utility models ("Gebrauchsmuster") are already publicly available as of their date of entry in the Register of utility models ("Eintragungstag"), which precedes the date of announcement in the Patent Bulletin ("Bekanntmachung im Patentblatt"). The search report also cites documents in which doubts with regard to the fact of public availability (for "in-house state of the art", see F-II, 4.3) and doubts concerning the precise date of publication (see B-VI, 5.6 and G-IV, 7.5) of a document have not, or not fully, been removed (see B-VI, 5.6 and G-IV, 7.5).

If the applicant contests the public availability or assumed date of publication of the cited document, the examiner should consider whether to investigate the matter further. If the applicant shows sound reasons for doubting whether the document forms part of the "state of the art" in relation to his application and any further investigation does not produce evidence sufficient to remove that doubt, the examiner should not pursue the matter further. The only other problem likely to arise for the examiner is where:

(i) a document reproduces an oral description (e.g. a public lecture) or gives an account of a prior use (e.g. display at a public exhibition); and

(ii) only the oral description or lecture was publicly available before the "date of filing" of the European application, the document itself being published on or after this date.

In such cases, the examiner should start with the assumption that the document gives a true account of the earlier lecture, display or other event and should therefore regard the earlier event as forming part of the "state of the art". If, however, the applicant gives sound reasons for contesting the truth of the account given in the document then again the examiner should not pursue the matter further.

2. Enabling disclosures

Subject-matter can only be regarded as having been made available to the public, and therefore as comprised in the state of the art pursuant to Art. 54(1), if the information given to the skilled person is sufficient to enable him, at the relevant date (see G-VI, 3), to practise the technical teaching which is the subject of the disclosure, taking into account also the general knowledge at that time in the field to be expected of him (see T 26/85, T 206/83 and T 491/99).

Where a prior art document discloses subject-matter which is relevant to the novelty and/or inventive step of the claimed invention, the disclosure of that document must be such that the skilled person can reproduce that subject-matter using common general knowledge (see G-VII, 3.1). Subject-matter does not necessarily belong to the common general knowledge simply because it has been disclosed in the state of the art: in particular, if the information can only be obtained after a comprehensive search, it cannot be considered to belong to the common general knowledge and cannot be used to complete the disclosure (see T 206/83).

For example, a document discloses a chemical compound (identified by name or by structural formula), indicating that the compound may be produced by a process defined in the document itself. The document, however, does not indicate how to obtain the starting materials and/or reagents used in the process. If the skilled person moreover cannot obtain these starting materials or reagents on the basis of common general knowledge (e.g. from text books), the

document is insufficiently disclosed with respect to that compound. Hence, it is not considered to belong to the state of the art according to Art. 54(2) (at least in as far as it relates to that compound) and consequently it does not prejudice the patentability of the claimed invention.

If, on the other hand, the skilled person knows how to obtain the starting materials and reagents (e.g. they are commercially available, or are well-known and appear in reference text books), the document is sufficiently disclosed with respect to the compound and therefore belongs to the state of the art according to Art. 54(2). The examiner can then validly rely upon this document to raise objections against the claimed invention.

3. Date of filing or priority date as effective date

It should be noted that "date of filing" in Art. 54(2) and (3) is to be interpreted as meaning the date of priority in appropriate cases (see F-VI, 1.2). It should be remembered that different claims, or different alternatives claimed in one claim, may have different effective dates, i.e. the date of filing or (one of) the claimed priority date(s). The question of novelty must be considered against each claim (or part of a claim where a claim specifies a number of alternatives) and the state of the art in relation to one claim or one part of a claim may include matter, e.g. an intermediate document (see B-X, 9.2.4), which cannot be cited against another claim or another alternative in the same claim because it has an earlier effective date. *Art. 89*

The priority right of the application being examined or the patent being opposed may also be lost as a result of failure to provide a translation of the priority when requested in accordance with Rule 53(3) (see A-III, 6.8 and sub-sections).

Of course, if all the matter in the state of the art was made available to the public before the date of the earliest priority document, the examiner need not (and should not) concern himself with the allocation of effective dates.

If the applicant files missing parts of the description, or drawings (see A-II, 5.1), late under Rule 56, the accorded date of the application is the date of filing of these missing elements under Rule 56(2) (see A-II, 5.3), unless they are completely contained in the priority document and the requirements given in Rule 56(3) are satisfied (see A-II, 5.4), in which case the original filing date is maintained. The date of the application as a whole is thus either the date of filing of the missing elements or the original filing date. *Rule 56*

Claims filed in response to a communication under Rule 58 do not result in a change in the filing date of the application (see A-III, 15), as they are considered as amendments to the application as filed (see H-IV, 2.3.3). *Rule 58*

4. Documents in a non-official language

If the applicant

(i) disputes the relevance of a document in a non-official language cited in the search report (for procedure at the search stage, see B-X, 9.1.2 and 9.1.3), and

(ii) gives specific reasons,

the examiner should consider whether, in the light of these reasons and of the other prior art available to him, he is justified in pursuing the matter. If so, he should obtain a translation of the document (or merely the relevant part of it if that can be easily identified). If he remains of the view that the document is relevant, he should send a copy of the translation to the applicant with the next official communication.

4.1 Machine translations

In order to overcome the language barrier constituted by a document in an unfamiliar non-official language, it might be appropriate for the examiner to rely on a machine translation of said document (see T 991/01), which should be sent to the applicant (see B-X, 9.1.3). If only part of the translated document is relevant, the particular passage relied upon should be identified (see B-XI, 3.2). A translation has to serve the purpose of rendering the meaning of the text in a familiar language (see B-X, 9.1.3). Therefore mere grammatical or syntactical errors which have no impact on the possibility of understanding the content do not hinder its qualification as a translation (see T 287/98).

A general statement that machine translations as such cannot be trusted is not sufficient to invalidate the probatory value of the translation. If a party objects to the use of a specific machine translation, that party bears the burden of adducing evidence (in the form of, for instance, an improved translation of the whole or salient parts of the document) showing the extent to which the quality of the machine translation is defective and should therefore not be relied upon.

When the party provides substantiated reasoning for questioning the objections raised based on the translated text, the examiner will have to take these reasons into account, similarly to when the publication date is questioned (see G-IV, 7.5.3).

5. Conflict with other European applications

5.1 State of the art pursuant to Art. 54(3)

Art. 54(3)
Art. 56
Art. 89
Art. 85

The state of the art also comprises the content of other European applications filed or validly claiming a priority date earlier than – but published under Art. 93 on or after – the date of filing or valid date of priority of the application being examined. Such earlier applications are part of the state of the art only when considering novelty and not when

considering inventive step. The "date of filing" referred to in Art. 54(2) and (3) is thus to be interpreted as meaning the date of priority in appropriate cases (see F-VI, 1.2). By the "content" of a European application is meant the whole disclosure, i.e. the description, drawings and claims, including:

(i) any matter explicitly disclaimed (with the exception of disclaimers for unworkable embodiments);

(ii) any matter for which an allowable reference (see F-III, 8, penultimate paragraph) to other documents is made; and

(iii) prior art insofar as explicitly described.

However, the "content" does not include any priority document (the purpose of such document being merely to determine to what extent the priority date is valid for the disclosure of the European application (see F-VI, 1.2)) nor, in view of Art. 85, the abstract (see F-II, 2).

It is important to note that it is the content of the earlier application as filed which is to be considered when applying Art. 54(3). Where an application is filed in a non-official language as permitted by Art. 14(2) (see A-VII, 1.1), it may happen that matter is erroneously omitted from the translation in the language of the proceedings and not published under Art. 93 in that language. Even in this case, it is the content of the original text which is relevant for the purposes of Art. 54(3).

5.1.1 Requirements

Whether a published European application can be a conflicting application under Art. 54(3) is determined firstly by its filing date and the date of its publication; the former must be before the filing or valid priority date of the application under examination, the latter must be on or after that date. If the published European application claims priority, the priority date replaces the filing date (Art. 89) for that subject-matter in the application which corresponds to the priority application. If a priority claim was abandoned or otherwise lost with effect from a date prior to publication, the filing date and not the priority date is relevant, irrespective of whether or not the priority claim might have conferred a valid priority right.

Further it is required that the conflicting application was still pending at its publication date (see J 5/81). If the application was withdrawn or otherwise lost before the date of publication, but published because the preparations for publication had been completed, the publication has no effect under Art. 54(3), but only under Art. 54(2). Art. 54(3) must be interpreted as referring to the publication of a "valid" application, i.e. a European patent application in existence at its publication date.

Changes taking effect after the date of publication (e.g. withdrawal of a designation or withdrawal of the priority claim or loss of the priority right

for other reasons) do not affect the application of Art. 54(3) (see H-III, 4.2 for transitional provisions concerning Art. 54(4) EPC 1973 and A-III, 11.1 and 11.3 for transitional arrangements concerning non-payment of designation fees for applications filed before 1 April 2009).

5.1.2 Accorded date of filing still subject to review

The prior art considered by the examiner might comprise documents (European or international patent applications) for which the accorded date of filing may still be under review before the EPO. This might be the case, for instance, when:

(i) a European patent application contains parts of the description and/or drawings filed under Rule 56, or

(ii) an international patent application contains elements or parts of the description, drawings or claims filed under Rule 20.5 or 20.6 PCT.

The examiner should check whether a final decision on the accorded date of filing has already been taken before considering the documents as being state of the art under Art. 54(3). If the date of filing has not yet been established, the examiner should temporarily deal with the documents (if relevant for assessing the patentability of the claimed subject-matter) as if their accorded date of filing were correct, revisiting the issue at a later point in time.

5.2 Euro-PCT applications

Art. 153
Rule 165

The above principles also apply to PCT applications designating EP, but with an important difference. Art. 153, in conjunction with Rule 165, makes it clear that a PCT application is not included in the state of the art for the purposes of Art. 54(3) unless the PCT applicant has paid the required filing fee under Rule 159(1)(c) and has supplied the PCT application to the EPO in English, French or German (this means that a translation is required where the PCT application was published in Japanese, Chinese, Spanish, Russian, Korean, Portuguese or Arabic).

5.3 Commonly designated States

See H-III, 4.2 for the transitional applicability of Art. 54(4) EPC 1973 to applications which are pending on 13 December 2007 and patents which have already been granted on that date.

5.4 Double patenting

The EPC does not deal explicitly with the case of co-pending European applications of the same effective date filed by the same applicant. However, it is an accepted principle in most patent systems that two patents cannot be granted to the same applicant for one invention. The Enlarged Board of Appeal has accepted obiter dictum that the principle of the prohibition on double patenting is based on the notion that an applicant has no legitimate interest in proceedings leading to the grant of a second patent for the same subject-matter if he already possesses

one granted patent for that subject-matter (see G 1/05, and G 1/06). It is permissible to allow an applicant to proceed with two applications having the same description which do not claim the same subject-matter (see also T 2461/10). The applicant may, for example, be interested in obtaining a first quicker protection for a preferred embodiment and pursue the general teaching in a divisional application (see G 2/10). However, in the rare case in which there are two or more European applications from the same applicant definitively designating the same State or States (by confirming the designation through payment of the relevant designation fee) and the claims of those applications have the same filing or priority date and relate to the same invention, the applicant should be told that he must either amend one or more of the applications in such a manner that the subject-matter of the claims of the applications is not identical, or choose which one of those applications he wishes to proceed to grant. If he does not do so, once one of the applications is granted, the other(s) will be refused under Art. 97(2) in conjunction with Art. 125. If the claims of those applications are merely partially overlapping, no objection should be raised (see T 877/06). Should two applications of the same effective date be received from two different applicants, each must be allowed to proceed as though the other did not exist.

6. Conflict with national rights of earlier date

Rule 138

Where a national right of an earlier date exists in a Contracting State designated in the application, there are several possibilities of amendment open to the applicant. First, he may simply withdraw that designation from his application for the Contracting State of the national right of earlier date. Second, for such State, he may file claims which are different from the claims for the other designated States. Third, the applicant can limit his existing set of claims in such a manner that the national right of earlier date is no longer relevant.

Amendment of the application to take account of prior national rights should be neither required nor suggested (see also H-III, 4.5). However, if the claims have been amended, then amendment of the description and drawings should be required if necessary to avoid confusion.

7. State of the art made available to the public "by use or in any other way"

7.1 Types of use and instances of state of the art made available in any other way

Use may be constituted by producing, offering, marketing or otherwise exploiting a product, or by offering or marketing a process or its application or by applying the process. Marketing may be effected, for example, by sale or exchange.

The state of the art may also be made available to the public in other ways, as for example by demonstrating an object or process in specialist training courses or on television.

Availability to the public in any other way also includes all possibilities which technological progress may subsequently offer of making available the aspect of the state of the art concerned.

Instances of public prior use or availability in any other way will typically be raised in opposition proceedings. While they may arise in examination, they are so rare that the following guidelines are addressed to opposition divisions.

7.2 Matters to be determined by the Opposition Division as regards use

When dealing with an allegation that an object or process has been used in such a way that it is comprised in the state of the art, the Opposition Division will have to determine the following details:

(i) the date on which the alleged use occurred, i.e. whether there was any instance of use before the relevant date (prior use);

(ii) what has been used, in order to determine the degree of similarity between the object used and the subject-matter of the European patent; and

(iii) all the circumstances relating to the use, in order to determine whether and to what extent it was made available to the public, as for example the place of use and the form of use. These factors are important in that, for example, the details of a demonstration of a manufacturing process in a factory or of the delivery and sale of a product may well provide information as regards the possibility of the subject-matter having become available to the public.

On the basis of the submissions and the evidence already submitted, e.g. documents confirming sale, or affidavits related to the prior use, the Opposition Division will first establish the relevance of the alleged prior use. If on the basis of this assessment it is of the opinion that the prior use is sufficiently substantiated and relevant, it may decide on the opposition using the submissions and the evidence, if the patentee does not contest the prior use. If the patentee does contest it or certain circumstances of it, the Division will need to take further evidence, if offered (e.g. hearing witnesses or performing an inspection) for those facts which are relevant to the case and which cannot yet be considered proven on the basis of the evidence already submitted. Evidence is always taken under participation of the parties, normally in oral proceedings. For details concerning means of evidence see E-III, 1.2.

7.2.1 General principles

Subject-matter should be regarded as made available to the public by use or in any other way if, at the relevant date, it was possible for members of the public to gain knowledge of the subject-matter and there was no bar of confidentiality restricting the use or dissemination

of such knowledge (see also G-IV, 1 with reference to written descriptions). This may, for example, arise if an object is unconditionally sold to a member of the public, since the buyer thereby acquires unlimited possession of any knowledge which may be obtained from the object. Even where in such cases the specific features of the object may not be ascertained from an external examination, but only by further analysis, those features are nevertheless to be considered as having been made available to the public. This is irrespective of whether or not particular reasons can be identified for analysing the composition or internal structure of the object. These specific features only relate to the intrinsic features. Extrinsic characteristics, which are only revealed when the product is exposed to interaction with specifically chosen outside conditions, e.g. reactants or the like, in order to provide a particular effect or result or to discover potential results or capabilities, therefore point beyond the product *per se* as they are dependent on deliberate choices being made. Typical examples are the first or further application as a pharmaceutical product of a known substance or composition (see Art. 54(4) and (5)) and the use of a known compound for a particular purpose, based on a new technical effect (see G 2/88). Thus, such characteristics cannot be considered as already having been made available to the public (see G 1/92).

If, on the other hand, an object could be seen in a given place (a factory, for example) to which members of the public not bound to secrecy, including persons with sufficient technical knowledge to ascertain the specific features of the object, had access, all knowledge which an expert was able to gain from a purely external examination is to be regarded as having been made available to the public. In such cases, however, all concealed features which could be ascertained only by dismantling or destroying the object will not be deemed to have been made available to the public.

7.2.2 Agreement on secrecy

The basic principle to be adopted is that subject-matter has not been made available to the public by use or in any other way if there is an express or tacit agreement on secrecy which has not been broken, or if the circumstances of the case are such that such secrecy derives from a relationship of good faith or trust. Good faith and trust are factors which may occur in contractual or commercial relationships. Reference should be made to the particular case of a non-prejudicial disclosure arising from an evident abuse in relation to the applicant, in accordance with Art. 55(1)(a) (see below, G-IV, 7.3.2; G-V).

7.2.3 Use on non-public property

As a general rule, use on non-public property, for example in factories and barracks, is not considered as use made available to the public, because company employees and soldiers are usually bound to secrecy, save in cases where the objects or processes used are exhibited, explained or shown to the public in such places, or where specialists not bound to secrecy are able to recognise their essential

features from the outside. Clearly the above-mentioned "non-public property" does not refer to the premises of a third party to whom the object in question was unconditionally sold or the place where the public could see the object in question or ascertain features of it (see the examples in G-IV, 7.2.1 above).

7.2.4 Example of the accessibility of objects used

A press for producing light building (hard fibre) boards was installed in a factory shed. Although the door bore the notice "Unauthorised persons not admitted", customers (in particular dealers in building materials and clients who were interested in purchasing light building boards) were given the opportunity of seeing the press although no form of demonstration or explanation was given. An obligation to secrecy was not imposed as, according to witnesses, the company did not consider such visitors as a possible source of competition. These visitors were not genuine specialists, i.e. they did not manufacture such boards or presses, but were not entirely laymen either. In view of the simple construction of the press, the essential features of the invention concerned were bound to be evident to anyone observing it. There was therefore a possibility that these customers, and in particular the dealers in building materials, would recognise these essential features of the press and, as they were not bound to secrecy, they would be free to communicate this information to others.

7.2.5 Example of the inaccessibility of a process

The subject of the patent concerns a process for the manufacture of a product. As proof that this process had been made available to the public by use, a similar already known product was asserted to have been produced by the process claimed. However, it could not be clearly ascertained, even after an exhaustive examination, by which process it had been produced.

7.3 State of the art made available by means of oral description

7.3.1 Cases of oral description

Art. 54(2) The state of the art is made available to the public by oral description when facts are unconditionally brought to the knowledge of members of the public in the course of a conversation or a lecture or by means of radio, television or sound reproduction equipment (tapes and records).

7.3.2 Non-prejudicial oral description

Art. 55(1)(a) The state of the art will not be affected by oral descriptions made by and to persons who were bound to, and preserved, secrecy, nor by an oral disclosure which was made no earlier than six months before the filing of the European patent application and which derives directly or indirectly from an evident abuse in relation to the applicant or his legal predecessor. In determining whether evident abuse has occurred, note G-V, 3.

7.3.3 Matters to be determined by the Opposition Division in cases of oral description

Once again, in such cases the following details will have to be determined:

(i) when the oral description took place;

(ii) what was described orally; and

(iii) whether the oral description was made available to the public; this will also depend on the type of oral description (conversation, lecture) and on the place at which the description was given (public meeting, factory hall; see also G-IV, 7.2(iii)).

7.4 State of the art made available to the public in writing or by any other means

For this state of the art, details equivalent to those defined in G-IV, 7.3.3 have to be determined if they are not clear from the written or other disclosure itself or if they are contested by a party.

If information is made available by means of a written description and use or by means of a written and oral description, but only the use or the oral description is made available before the relevant date, then in accordance with G-IV, 1, the subsequently published written description may be deemed to give a true account of that oral description or use, unless the proprietor of the patent can give good reason why this should not be the case. In this case, the opponent must adduce proof to the contrary in respect of the reasons given by the proprietor of the patent. Caution should be exercised when considering the type of evidence presented to substantiate the content of an oral description. For example, a report of a lecture written by the lecturer himself may not be an accurate account of what was in fact conveyed to the public. Similarly, a script from which the lecturer purportedly read may not actually have been completely and comprehensibly read (see T 1212/97).

7.5 Internet disclosures

As a matter of principle, disclosures on the internet form part of the state of the art according to Art. 54(2). Information disclosed on the internet or in online databases is considered to be publicly available as of the date the information was publicly posted. Internet websites often contain highly relevant technical information. Certain information may even be available only on the internet from such websites. This includes, for example, online manuals and tutorials for software products (such as video games) or other products with a short life cycle. Hence for the sake of a valid patent it is often crucial to cite publications only obtainable from such internet websites.

7.5.1 Establishing the publication date

Establishing a publication date has two aspects. It must be assessed separately whether a given date is indicated correctly and whether the

content in question was indeed made available to the public as of that date.

The nature of the internet can make it difficult to establish the actual date on which information was made available to the public: for instance, not all web pages mention when they were published. Also, websites are easily updated, yet most do not provide any archive of previously displayed material, nor do they display records which enable members of the public - including examiners - to establish precisely what was published and when.

Neither restricting access to a limited circle of people (e.g. by password protection) nor requiring payment for access (analogous to purchasing a book or subscribing to a journal) prevent a web page from forming part of the state of the art. It is sufficient if the web page is in principle available without any bar of confidentiality.

Finally, it is theoretically possible to manipulate the date and content of an internet disclosure (as it is with traditional documents). However, in view of the sheer size and redundancy of the content available on the internet, it is considered very unlikely that an internet disclosure discovered by an examiner has been manipulated. Consequently, unless there are specific indications to the contrary, the date can be accepted as being correct.

7.5.2 Standard of proof

When an internet document is cited against an application or patent, the same facts are to be established as for any other piece of evidence, including standard paper publications (see G-IV, 1). This evaluation is made according to the principle of "free evaluation of evidence" (see T 482/89, and T 750/94). That means that each piece of evidence is given an appropriate weight according to its probative value, which is evaluated in view of the particular circumstances of each case. The standard for assessing these circumstances is the balance of probabilities. According to this standard, it is not sufficient that the alleged fact (e.g. the publication date) is merely probable; the examining division must be convinced that it is correct. It does mean, however, that proof beyond reasonable doubt ("up to the hilt") of the alleged fact is not required.

The publication dates of internet disclosures submitted by a party to opposition proceedings are assessed according to the same principles as are applied in examination proceedings, i.e. they should be assessed in view of the specific circumstances of the case. In particular, the timing of the submission as well as the interests of the party submitting the disclosure should also be taken into account.

In many cases, internet disclosures contain an explicit publication date which is generally considered reliable. Such dates are accepted at face value, and the burden of proof will be on the applicant to show otherwise. Circumstantial evidence may be required to establish or

confirm the publication date (see G-IV, 7.5.4). If the examiner comes to the conclusion that - on the balance of probabilities - it has been established that a particular document was available to the public at a particular date, this date is used as publication date for the purpose of examination.

7.5.3 Burden of proof

It is a general principle that, when raising objections, the burden of proof lies initially with the examiner. This means that objections must be reasoned and substantiated, and must show that, on the balance of probabilities, the objection is well-founded. If this is done, it is then up to the applicant to prove otherwise - the burden of proof shifts to the applicant.

If an applicant provides reasons for questioning the alleged publication date of an internet disclosure, the examiner will have to take these reasons into account. If the examiner is no longer convinced that the disclosure forms part of the state of the art, he will either have to present further evidence to maintain the disputed publication date or will not use this disclosure further as prior art against the application.

The later the examiner sets out to obtain such evidence, the more difficult it may become. The examiner should use his judgment to decide whether it is worth spending a short amount of time at the search stage to find further evidence in support of the publication date.

If an applicant refutes the publication date of an internet disclosure with no reasoning or merely with generic statements about the reliability of internet disclosures, this argument will be given minimal weight and is therefore unlikely to sway the examiner's opinion.

While the dates and content of internet disclosures can be taken at face value, there are of course differing degrees of reliability. The more reliable a disclosure, the harder it will be for the applicant to prove that it is incorrect. The following sections look at the reliability of various popular types of internet disclosure.

7.5.3.1 Technical journals

Of particular importance for examiners are online technical journals from scientific publishers (e.g. IEEE, Springer, Derwent). The reliability of these journals is the same as that of traditional paper journals, i.e. very high.

It should be noted that the internet publication of a particular issue of a journal may be earlier than the date of publication of the corresponding paper version. Furthermore, some journals pre-publish on the internet manuscripts which have been submitted to them, but which have not yet been published, and in some cases before they have even been approved for paper publication (for example, the "Geophysics" journal). If the journal then does not approve the manuscript for publication, this pre-publication of the manuscript may be the only

disclosure of its content. Examiners should also remember that the pre-published manuscript may differ from the final, published version.

Where the given publication date of an online journal publication is too vague (e.g. only the month and year is known), and the most pessimistic possibility (the last day of the month) is too late, the examiner may request the exact publication date. Such a request may be made directly through a contact form that the publisher may offer on the internet, or via the EPO library.

7.5.3.2 Other "print equivalent" publications

Many sources other than scientific publishers are generally deemed to provide reliable publication dates. These include for example publishers of newspapers or periodicals, or television or radio stations. Academic institutions (such as academic societies or universities), international organisations (such as the European Space Agency ESA), public organisations (such as ministries or public research agencies) or standardisation bodies also typically fall into this category.

Some universities host so-called eprint archives to which authors submit reports on research results in electronic form before they are submitted or accepted for publication by a conference or journal. In fact, some of these reports are never published anywhere else. The most prominent such archive is known as arXiv.org (*www.arxiv.org*, hosted by the Cornell University Library), but several others exist, e.g. the Cryptology eprint archive (eprint.iacr.org, hosted by the International Association for Cryptology Research). Some such archives crawl the internet to automatically retrieve publications which are publicly available from researchers' web pages, such as Citeseer or ChemXseer (citeseer.ist.psu.edu and chemxseer.ist.psu.edu, both hosted by Pennsylvania State University).

Companies, organisations or individuals use the internet to publish documents that had previously been published on paper. These include manuals for software products such as video games, handbooks for products such as mobile phones, product catalogues or price lists and white papers on products or product families. Evidently, most of these documents address the public - e.g. actual or potential customers - and are thus meant for publication. Hence the date given can be taken as a date of publication.

7.5.3.3 Non-traditional publications

The internet is also used to exchange and publish information in ways which did not exist before, via, for example, Usenet discussion groups, blogs, e-mail archives of mailing lists or wiki pages. Documents obtained from such sources also constitute prior art, although it may be more involved to establish their publication date, and their reliability may vary.

The content of a transmitted e-mail cannot be considered to be public merely for the reason that it could have been intercepted (T 2/09).

Computer-generated timestamps (usually seen, for example, on blogs, Usenet or the version history available from wiki pages) can be considered as reliable publication dates. While such dates could have been generated by an imprecise computer clock, this should be weighed against the fact that in general many internet services rely on accurate timing and will often stop functioning if time and date are incorrect. In the absence of indications to the contrary, the frequently used "last modified" date can be treated as the publication date.

7.5.4 Disclosures which have no date or an unreliable date

Where an internet disclosure is relevant for examination but does not give any explicit indication of the publication date in the text of the disclosure, or if an applicant has shown that a given date is unreliable, the examiner may try to obtain further evidence to establish or confirm the publication date. Specifically, he may consider using the following information:

(a) Information relating to a web page available from an internet archiving service. The most prominent such service is the Internet Archive accessible through the so-called "Wayback Machine" (www.archive.org). The fact that the Internet Archive is incomplete does not detract from the credibility of the data it does archive. It is also noted that legal disclaimers relating to the accuracy of any supplied information are routinely used on websites (even respected sources of information such as Espacenet or IEEE), and these disclaimers should not be taken to reflect negatively on the websites' actual accuracy.

(b) Timestamp information relating to the history of modifications applied to a file or web page (for example, as available for wiki pages such as Wikipedia and in version control systems as used for distributed software development).

(c) Computer-generated timestamp information as available from file directories or other repositories, or as automatically appended to content (e.g. forum messages and blogs).

(d) Indexing dates given to the web page by search engines (e.g. from the Google cache). These will be later than the actual publication date of the disclosure, since the search engines take some time to index a new website.

(e) Information relating to the publication date embedded in the internet disclosure itself. Date information is sometimes hidden in the programming used to create the website but is not visible in the web page as it appears in the browser. Examiners may, for example, consider the use of computer forensic tools to retrieve such dates. In order to allow a fair evaluation of the accuracy of the date by both the applicant and the examiner, these dates should be used only if the examiner knows how they were obtained and can communicate this to the applicant.

(f) Information about replication of the disclosure at several sites (mirror sites) or in several versions.

It may also be possible to make enquiries with the owner or the author of the website when trying to establish the publication date to a sufficient degree of certainty. The probative value of statements so obtained will have to be assessed separately.

If no date can be obtained (other than the date of retrieval by the examiner, which will be too late for the application in question), the disclosure cannot be used as prior art during examination. If the examiner considers that a publication, although undated, is highly relevant to the invention and can therefore be considered to be of interest to the applicant or third parties, he may choose to cite the publication in the search report as an "L" document. The search report and the written opinion should explain why this document was cited. Citing the disclosure will also make it citable against future applications, using the date of retrieval as the date of publication.

7.5.5 Problematic cases

Web pages are sometimes divided into frames the content of which is drawn from different sources. Each of these frames may have its own publication date which may have to be checked. In an archiving system, for instance, it may happen that one frame contains the archived information with an old publishing date whereas other frames contain commercials generated at the time of retrieval. The examiner should ensure that he uses the right publication date, i.e. that the cited publication date refers to the intended content.

When a document retrieved from the Internet Archive contains links, there is no guarantee that the links point to documents archived on the same date. It may even happen that the link does not point to an archived page at all but to the current version of the web page. This may in particular be the case for linked images, which are often not archived. It may also happen that archived links do not work at all.

Some internet addresses (URLs) are not persistent, i.e. they are designed to work only during a single session. Long URLs with seemingly random numbers and letters are indicative of these. The presence of such a URL does not prevent the disclosure being used as prior art, but it does mean that the URL will not work for other people (e.g. the applicant when he receives the search report). For non-persistent URLs, or if, for other reasons, it is considered prudent, the examiner should indicate how he arrived at that specific URL from the main home page of the respective website (i.e. which links were followed, or which search terms were used).

7.5.6 Technical details and general remarks

When printing a web page, care should be taken that the complete URL is clearly legible. The same applies to the relevant publication date on a web page.

It should be borne in mind that publication dates may be given in different formats, especially in either the European format dd/mm/yyyy, the US format mm/dd/yyyy or the ISO format yyyy/mm/dd. Unless the format is explicitly indicated, it will be impossible to distinguish between the European format and the US format for days 1-12 of each month.

If a publication date is close to the relevant priority date, the time zone of publication may be crucial to interpret a publication date.

The examiner should always indicate the date on which the web page was retrieved. When citing internet disclosures, he should explain the prior art status of the document, e.g. how and where he obtained the publication date (for example, that the eight digits in the URL represent the date of archiving in the format yyyymmdd), and any other relevant information (for example, where two or more related documents are cited, how they are related, indicating for instance that following link 'xyz' on the first document leads to the second document).

7.6 Standards and standard preparatory documents

Standards define sets of characteristics or qualities for products, processes, services or materials (e.g. the properties of an interface) and are usually developed by Standards Development Organisations (SDOs) by consensus amongst the relevant economic stakeholders.

Final standards themselves in principle form part of the state of the art under Art. 54(2), although there are important exceptions. One of these relates to private standards consortia (e.g. in the field of CD-ROM, DVD and Blu-ray discs), which do not publish the final standards but make them available to the interested circles subject to acceptance of a non-disclosure agreement (categorically forbidding the recipients of the documents to disclose their content).

Before an SDO reaches agreement on the establishment or further development of a standard, various types of preparatory documents are submitted and discussed. These preparatory documents should be treated like any other written or oral disclosures, i.e. in order to qualify as prior art they must have been made available to the public prior to the filing or priority date without any bar of confidentiality. Thus if a standard preparatory document is cited against an application during search or examination, the same facts are to be established as for any other piece of evidence (see G-IV, 1 and T 738/04).

The existence of an explicit confidentiality obligation must be determined case by case on the basis of the documents allegedly setting forth this obligation (see T 273/02 and T 738/04). These may be general guidelines, directives or principles of the SDO concerned, licensing terms or a Memorandum of Understanding resulting from interaction between the SDOs and their members. In case of a general confidentiality clause, i.e. one that is not indicated on or in the relevant preparatory document itself, it must be established that the general confidentiality obligation actually extended to the document in question

until the relevant point in time. This does not however require the document itself to be explicitly marked as confidential (see T 273/02).

If the preparatory documents are available in the EPO's in-house databases or at freely accessible sources (for example, on the internet), the examiner is allowed to cite them in the search report and to refer to them during the procedure. The public availability of the documents, if at all necessary, may be further investigated during examination and opposition in accordance with the principles set out above.

While documents in the EPO's in-house databases are regarded as being available to the public, no general indication can be given for documents obtained from other sources.

Norms and standards are comparable with trademarks in that their content can vary with time. Therefore, they have to be identified properly by their version number and publication date (see also F-III, 7, F-IV, 4.8, and H-IV, 2.3.9).

8. Cross-references between prior art documents

If a document (the "primary" document) refers explicitly to another document (the "secondary" document) as providing more detailed information on certain features, the teaching of the latter is to be regarded as incorporated into the primary document if the document was available to the public on the publication date of the primary document (see T 153/85) (for the state of the art pursuant to Art. 54(3), see G-IV, 5.1 and F-III, 8, penultimate paragraph). The relevant date for novelty purposes, however, is always the date of the primary document (see G-IV, 3).

9. Errors in prior art documents

Errors may exist in prior art documents. If, using common general knowledge (see G-VII, 3.1), the skilled person can

(i) see at once that the disclosure of a relevant prior art document contains errors, and

(ii) identify what the only possible correction should be,

then the errors in the disclosure do not affect its relevance as prior art. The document can thus be considered to contain the correction when assessing its relevance to patentability (see T 591/90).

For possible errors concerning compound records in online databases, see B-VI, 6.5.

Chapter V – Non-prejudicial disclosures

1. General

There are two specific instances (and these are the only two) in which a prior disclosure of the invention is not taken into consideration as part of the state of the art, viz. where the disclosure was due to, or in consequence of: *Art. 55(1)*

(i) an evident abuse in relation to the applicant or his legal predecessor – e.g. the invention was derived from the applicant and disclosed against his wish; or *Art. 55(1)(a)*

(ii) the display of the invention by the applicant or his legal predecessor at an officially recognised international exhibition as defined in Art. 55(1)(b). *Art. 55(1)(b)*

2. Time limit

An essential condition, in both instances G-V, 1(i) and (ii), is that the disclosure in point must have taken place not earlier than six months preceding the filing of the application. For calculating the six-month period the relevant date is that of the actual filing date of the European patent application, not the priority date (G 3/98, and G 2/99).

3. Evident abuse

Regarding instance G V, 1(i), the disclosure might be made in a published document or in any other way. As a particular instance, the disclosure might be made in a European application of earlier priority date. Thus, for example, a person B who has been told of A's invention in confidence, might himself apply for a patent for this invention. If so, the disclosure resulting from the publication of B's application will not prejudice A's rights provided that A has already made an application, or applies within six months of such publication. In any event, having regard to Art. 61, B may not be entitled to proceed with his application (see G-VI, 2).

For "evident abuse" to be established, there must be, on the part of the person disclosing the invention, either actual intent to cause harm or actual or constructive knowledge that harm would or could ensue from this disclosure (see T 585/92).

4. International exhibition

In instance G-V, 1(ii), the application must be filed within six months of the disclosure of the invention at the exhibition if the display is not to prejudice the application. Furthermore, the applicant must state, at the time of filing the application, that the invention has been so displayed, and must also file a supporting certificate within four months, giving the particulars required by Rule 25 (see A-IV, 3). The exhibitions recognised are published in the Official Journal. *Art. 55(2)* *Rule 25*

Chapter VI – Novelty

1. State of the art pursuant to Art. 54(2)

An invention is considered to be new if it does not form part of the state of the art. For a definition of "state of the art", see G-IV, 1. It should be noted that in considering novelty (as distinct from inventive step, see G-VII, 8), it is not permissible to combine separate items of prior art together. It is also not permissible to combine separate items belonging to different embodiments described in one and the same document, unless such combination has specifically been suggested (see T 305/87).

The concept of "seriously contemplating" (see G-VI, 8(iii)) may be used to assess novelty in the case of overlapping ranges of claimed subject-matter and the prior art (see T 666/89). This concept is fundamentally different from the concept used for assessing inventive step, namely whether the skilled person "would have tried, with reasonable expectation of success", to bridge the technical gap between a particular piece of prior art and a claim whose inventiveness is in question (see G-VII, 5.3), because in order to establish anticipation, there cannot be such a gap.

Furthermore, any matter explicitly disclaimed (with the exception of disclaimers which exclude unworkable embodiments) and prior art acknowledged in a document, insofar as explicitly described therein, are to be regarded as incorporated in the document.

It is further permissible to use a dictionary or similar document of reference in order to interpret a special term used in a document.

2. Implicit features or well-known equivalents

A document takes away the novelty of any claimed subject-matter derivable directly and unambiguously from that document including any features implicit to a person skilled in the art in what is expressly mentioned in the document, e.g. 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. The limitation to subject-matter "derivable directly and unambiguously" from the document is important. Thus, when considering novelty, it is not correct to interpret the teaching of a document as embracing well-known equivalents which are not disclosed in the documents; this is a matter of obviousness.

3. Relevant date of a prior document

In determining novelty, a prior document should be read as it would have been read by a person skilled in the art on the relevant date of the document. By "relevant" date is meant the publication date in the case of a previously published document and the date of filing (or priority date, where appropriate) in the case of a document according to Art. 54(3) (see G-IV, 5.1).

4. Enabling disclosure of a prior document

Subject-matter described in a document can only be regarded as having been made available to the public, and therefore as comprised in the state of the art pursuant to Art. 54(1), if the information given therein to the skilled person is sufficient to enable him, at the relevant date of the document (see G-VI, 3), to practise the technical teaching which is the subject of the document, taking into account also the general knowledge at that time in the field to be expected of him (see T 26/85, T 206/83 and T 491/99).

Similarly, it should be noted that a chemical compound, the name or formula of which is mentioned in a prior-art document, is not thereby considered as known, unless the information in the document, together, where appropriate, with knowledge generally available on the relevant date of the document, enables it to be prepared and separated or, for instance in the case of a product of nature, only to be separated.

5. Generic disclosure and specific examples

In considering novelty, it should be borne in mind that a generic disclosure does not usually take away the novelty of any specific example falling within the terms of that disclosure, but that a specific disclosure does take away the novelty of a generic claim embracing that disclosure, e.g. a disclosure of copper takes away the novelty of metal as a generic concept, but not the novelty of any metal other than copper, and one of rivets takes away the novelty of fastening means as a generic concept, but not the novelty of any fastening other than rivets.

6. Implicit disclosure and parameters

In the case of a prior document, the lack of novelty may be apparent from what is explicitly stated in the document itself. Alternatively, it may be implicit in the sense that, in carrying out the teaching of the prior document, the skilled person would inevitably arrive at a result falling within the terms of the claim. An objection of lack of novelty of this kind should be raised by the examiner only where there can be no reasonable doubt as to the practical effect of the prior teaching (for a second non-medical use, however, see G-VI, 7). Situations of this kind may also occur when the claims define the invention, or a feature thereof, by parameters (see F-IV, 4.11). It may happen that in the relevant prior art a different parameter, or no parameter at all, is mentioned. If the known and the claimed products are identical in all other respects (which is to be expected if, for example, the starting products and the manufacturing processes are identical), then in the first place an objection of lack of novelty arises. The burden of proof for an alleged distinguishing feature lies with the applicant. No benefit of doubt can be accorded if the applicant does not provide evidence in support of the allegations (see T 1764/06). If, on the other hand, the applicant is able to show, e.g. by appropriate comparison tests, that differences do exist with respect to the parameters, it is questionable whether the application discloses all the features essential to

manufacture products having the parameters specified in the claims (Art. 83).

7. Examination of novelty

In determining novelty of the subject-matter of claims, the examiner should have regard to the guidance given in F-IV, 4.5 to 4.21. He should remember that, particularly for claims directed to a physical entity, non-distinctive characteristics of a particular intended use should be disregarded (see F-IV, 4.13). For example, a claim to a substance X for use as a catalyst would not be considered to be novel over the same substance known as a dye, unless the use referred to implies a particular form of the substance (e.g. the presence of certain additives) which distinguishes it from the known form of the substance. That is to say, characteristics not explicitly stated, but implied by the particular use, should be taken into account (see the example of a "mold for molten steel" in F-IV, 4.13). For claims to a first medical use, see G-II, 4.2.

A known compound is not rendered novel merely because it is available with a different degree of purity if the purity can be achieved by conventional means (see T 360/07).

7.1 Second or further medical use of known pharmaceutical products

Where a substance or composition is already known to have been used in a "first medical use", it may still be patentable under Art. 54(5) for any second or further use in a method according to Art. 53(c), provided that said use is novel and inventive.

Art. 54(4) and (5) thus provide for an exception from the general principle that product claims can only be obtained for (absolutely) novel products. However, this does not mean that product claims for the first and further medical uses need not fulfil all other requirements of patentability, especially that of inventive step (see T 128/82).

A claim in the form "Use of substance or composition X for the treatment of disease Y..." will be regarded as relating to a method for treatment explicitly excluded from patentability under Art. 53(c) and therefore will not be accepted. A claim in the form "Substance X for use as a medicament" is acceptable, even if X is a known substance, but its use in medicine is not known. Likewise, it is acceptable to have a claim in the form "Substance X for use in the treatment of disease Y", provided that such a claim involves an inventive step over any prior art disclosing the use of X as a medicament.

Art. 82

If an application discloses for the first time a number of distinct surgical, therapeutic or diagnostic uses for a known substance or composition, normally in the one application independent claims each directed to the substance or composition for one of the various uses may be allowed; i.e. an a priori objection of lack of unity of invention should not, as a general rule, be raised (see F-V, 7).

A claim in the form "Use of a substance or composition X for the manufacture of a medicament for therapeutic application Z" is allowable for either a first or "subsequent" (second or further) such application ("Swiss-type" claim), if this application is new and inventive (see G 5/83) and has a filing or earliest priority date before 29 January 2011. For applications filed on or after that date, if the invention is characterised by a second (or further) therapeutic use of a medicament, such an invention cannot be expressed as a "Swiss-type" claim (see Notice from the EPO in OJ EPO 2010, 514).

The effect of the different claim formulations on patentability is summarised in the table below:

Examples			
#	Claim	Patentable?	Article
A	Use of product X for the treatment of asthma	No	53(c)
B	1. Product X for use as a medicament [X known as e.g. herbicide] 2. Product according to claim 1 for use in the treatment of asthma	Yes (even if X is a known product, but its use in medicine is not known)	54(4)
C	Product X for use in the treatment of cancer*	Yes (even if case B is prior art, provided that such a claim is inventive over B and any other prior art)	54(5)
D	Product X for use in the treatment of leukaemia*	Yes (even if cases B and C are prior art, provided that D is inventive over B and C and any other prior art because leukaemia is a specific type of cancer)	54(5)

* Note: The corresponding Swiss-type claims for cases C and D (required under EPC 1973) would be "The use of Product X for the manufacture of a medicament for the treatment of cancer/leukaemia".

In cases where an applicant simultaneously discloses more than one "subsequent" therapeutic use, claims of the above type directed to these different uses are allowable in the one application, but only if they form a single general inventive concept (Art. 82). Regarding use claims of the above type, it should also be noted that a mere pharmaceutical effect does not necessarily imply a therapeutical application. For instance, the selective occupation of a specific

receptor by a given substance cannot be considered in itself as a therapeutic application; indeed, the discovery that a substance selectively binds a receptor, even if representing an important piece of scientific knowledge, still needs to find an application in the form of a defined, real treatment of a pathological condition in order to make a technical contribution to the art and to be considered as an invention eligible for patent protection (see T 241/95). See also F-IV, 4.22, for the functional definition of a pathological condition.

7.1.1 Products that may be claimed for a further medical use

The scope of protection of use-related product claims under Art. 54(5) is limited to the substance or composition in the context of its medical use, which confers novelty and non-obviousness, if any, on the claimed product.

This principle applies only to substances and compositions and cannot be extended to other products. A claim directed to a device for an intended medical use (e.g. pacemaker or implantable chemical sensor for use in ...) must be construed as claiming a device which is suitable for that medical use (F-IV, 4.13).

7.1.2 Therapeutic uses pursuant to Art. 54(5)

The treatment of a disease with a substance or composition which is already known to be used for treating said disease, where the only difference from the known treatment is in the dosage regime, is a specific further medical use within the meaning of Art. 54(5) (see G 2/08). Thus, therapeutic uses of a substance/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 for example in the dosage, administration regime, group of subjects or route of administration (G 2/08).

A claim directed to the further therapeutic use of a substance/ composition should indicate the illness/disease to be treated, the nature of the therapeutic compound used for that purpose and, if relevant for establishing novelty and inventive step, the subject to be treated. If the further therapeutic use relates to a different therapy of the same disease using the same substance/composition, the claim should also define all technical features of the therapy giving rise to the desired technical effect (G 2/08).

An independent claim directed to a further therapeutic use of a substance/composition which is based on the use of said product in the treatment of a different disease should be formulated as follows:

Substance X or Composition comprising X	for use	in a method for the treatment of Y, or in the therapy of Y, or in a method of treating Y, or in a method of therapy of Y, or as a medicament defined by its function, (e.g. as an anti-inflammatory medicament)

The presence of the term "for use" is mandatory, to closely adhere to the wording of Art. 54(5).

If the further therapeutic use is based on the use of the same product in a different treatment of the same disease, the independent claim should be formulated as follows:

Substance X for use or Composition comprising X for use	in a method for the treatment of Y, or in the therapy of Y, or in a method of treating Y, or in a method of therapy of Y, or as a medicament defined by its function (e.g. as an anti-inflammatory medicament)	characterised in that/ wherein	other features (e.g. the substance /composition is administered topically, three times daily...)

Purpose-related product claims which do not define exclusively (see claim 4 in the table below) a medical use excluded from patentability under Art. 53(c) should be construed as claims directed to a product *per se* which is suitable for the claimed use.

The table below shows some examples of claims which do not define a further medical use within the meaning of Art. 53(c) ...

		... because ...
1. Substance X or Composition comprising X in/for	a method for the treatment of Y, or the therapy of Y, or a method of treating Y, or a method of therapy of Y, or the (topical) treatment of Y, or the (topical) therapy of Y	without the term "for use" it is not evident if the claim is directed to the product suitable for the specified use or if the claim is limited by the medical use

2. (Anti-inflammatory) medicament, or Pharmaceutical comprising substance X, or Composition comprising X	for topical treatment	the claim indicates neither a therapeutic role nor a therapeutic application of the claimed product. Moreover, without the term "for use" it is not evident if the claim is directed to the product suitable for the specified use or if the claim is limited by the medical use
3. Substance X or Composition comprising X	as an anti-inflammatory agent	without the term "for use" it is not evident if the claim is directed to the product suitable for the specified use or if the claim is limited by the medical use
4. Substance X or Composition comprising X	for use as an antifungal /antibacterial agent	the claim does not define a specific medical use of the claimed product. It encompasses non-medical uses, because antifungal/ antibacterial agents are also used in e.g. agriculture for treating plants

If the prior art discloses either the product *per se* in a form which could be considered suitable for the claimed use, or its first medical application, claims 1 to 4 would lack novelty. The novelty objection could be overcome by reformulating the claim as described above (first table of G-VI, 7.1.2).

These amendments may be proposed by the Examining Division in the Rule 71(3) communication without the need to consult the applicant beforehand (see C-V, 1.1, point (f)).

7.1.3 Diagnostic uses pursuant to Art. 54(5)

A suitable formulation of a diagnostic claim according to Art. 54(5) may read:

Substance X or Composition comprising X	for use in a method of diagnosis	"in vivo"	of disease Y

The wording "in vivo" limits the scope of the claim to diagnostic methods which are excluded from patentability pursuant to Art. 53(c).

Purpose-related product claims which do not define a diagnostic use excluded from patentability under Art. 53(c) should be construed as claims directed to a product *per se* which is suitable for the claimed use.

The following table shows some examples of claims which do not define a diagnostic use within the meaning of Art. 53(c):

1. Substance X or Composition comprising X	for use in the diagnosis of disease Y, or for use in the "in vitro"/"ex vivo" diagnosis of disease Y
2. Substance X or Composition comprising X	for use as a contrast agent for imaging blood flow

Claims 1 and 2 would lack novelty over prior art disclosing either the product *per se* in a form which could be considered suitable for the claimed use, or its first medical application.

Claim 1 could be reformulated as "Use of [...] in the "in vitro/ex vivo" diagnosis of disease Y". If the application as filed discloses, either explicitly or implicitly, that the claimed diagnostic methods are to be carried out "in vivo", the wording of claim 1 could also be limited to encompass only "in vivo" methods, as described above.

Claim 2 could be reformulated as "Use of [...] as contrast agent for imaging blood flow".

Claims 1 and 2 could also be reformulated as method claims, e.g. "A method for in vitro/ex vivo diagnosing disease Y using substance X [...]" or " A method for diagnosing disease Y in a sample by using substance X [...]" or "A method of imaging blood flow using substance X [...]".

These amendments may be proposed by the Examining Division in the Rule 71(3) communication without the need to consult the applicant beforehand (see C-V, 1.1, point (f)).

7.1.4 Surgical uses pursuant to Art. 54(5)

A claim defining a second surgical use may read "Substance X for use in a method of intracardiac catheterisation as a protector of blood vessel walls".

Purpose-related product claims which do not define a surgical use excluded from patentability under Art. 53(c) should be construed as claims directed to a product *per se* which is suitable for the claimed use.

The following table shows an example of a claim which does not define a surgical use within the meaning of Art. 53(c):

1. Substance X or Composition comprising X	for use in a method for hair removal by laser radiation

The claim would lack novelty over prior art disclosing either the product *per se* in a form which could be considered suitable for the claimed use, or its first medical application.

The claim could be reformulated as "Use of [...] for hair removal by laser radiation" or as "Method for removing hair by laser radiation by using substance X [...]".

This amendment may be proposed by the Examining Division in the Rule 71(3) communication without the need to consult the applicant beforehand (see C-V, 1.1, point (f)).

7.1.5 Dependent claims pursuant to Art. 54(5)

The wording of the dependent claims must clearly reflect their dependency on the independent claim. A suitable formulation may read:

Substance X or Composition comprising X	for use in the therapy of disease Y according to claim # or for use according to claim #	characterised in that/ wherein	other features (e.g. it is provided as water-soluble granulates)

In the following example, the dependent claim is not correctly formulated according to Art. 54(5).

Claim 1: Composition comprising X for use in the treatment of Y.

Claim 2: Composition according to claim 1, comprising 5 mg X.

The category of claim 2 is unclear and the dependency is doubtful. The claim appears to depend on a claim directed to a product *per se*.

The claim would also lack novelty over prior art disclosing a composition comprising 5 mg X, or a first medical application thereof.

The claim should be reformulated as indicated above by inserting "for use" between "Composition" and "according". This amendment may be proposed by the Examining Division in the Rule 71(3) communication without the need to consult the applicant beforehand (see C-V, 1.1, point (f)).

7.2 Second non-medical use

A claim to the use of a known compound for a particular purpose (second non-medical use) which is based on a technical effect should be interpreted as including that technical effect as a functional technical feature. Accordingly, said claim is not open to objection under Art. 54(1), provided that such technical feature has not previously been made available to the public (G 2/88, and G 6/88). The novelty of the use of the known compound for the known production of a known product cannot be deduced from a new property of the produced product. In such a case, the use of a compound for the production of a product has to be interpreted as a process for production of the product with the compound. It can be regarded as novel only if the process of production as such is novel (see T 1855/06). For claims to a second or further medical use, see G-II, 4.2.

8. Selection inventions

Selection inventions deal with the selection of individual elements, sub-sets, or sub-ranges, which have not been explicitly mentioned, within a larger known set or range.

(i) In determining the novelty of a selection, it has to be decided, whether the selected elements are disclosed in an individualised (concrete) form in the prior art (see T 12/81). A selection from a single list of specifically disclosed elements does not confer novelty. However, if a selection from two or more lists of a certain length has to be made in order to arrive at a specific combination of features then the resulting combination of features, not specifically disclosed in the prior art, confers novelty (the "two-lists principle"). Examples of such selections from two or more lists are the selection of:

(a) individual chemical compounds from a known generic formula whereby the compound selected results from the selection of specific substituents from two or more "lists" of substituents given in the known generic formula. The same applies to specific mixtures resulting from the selection of individual components from lists of components making up the prior art mixture;

(b) starting materials for the manufacture of a final product;

(c) sub-ranges of several parameters from corresponding known ranges.

(ii) A sub-range selected from a broader numerical range of the prior art is considered novel, if each of the following three criteria is satisfied (see T 198/84 and T 279/89):

(a) the selected sub-range is narrow compared to the known range;

(b) the selected sub-range is sufficiently far removed from any specific examples disclosed in the prior art and from the end-points of the known range;

(c) the selected range is not an arbitrary specimen of the prior art, i.e. not a mere embodiment of the prior art, but another invention (purposive selection, new technical teaching).

An effect occurring only in the claimed sub-range cannot in itself confer novelty on that sub-range. However, such a technical effect occurring in the selected sub-range, but not in the whole of the known range, can confirm that criterion (c) is met, i.e. that the invention is novel and not merely a specimen of the prior art. The meaning of "narrow" and "sufficiently far removed" has to be decided on a case-by-case basis. The new technical effect occurring within the selected range may also be the same effect as that attained with the broader known range, but to a greater extent.

(iii) In the case of overlapping ranges (e.g. numerical ranges, chemical formulae) of claimed subject-matter and the prior art the same principles apply for the assessment of novelty as in other cases, e.g. selection inventions (see T 666/89). It has to be decided which subject-matter has been made available to the public by a prior art disclosure and thus forms part of the state of the art. In this context, it is not only examples, but the whole content of the prior art document which has to be taken into consideration. As to overlapping ranges or numerical ranges of physical parameters, novelty is destroyed by an explicitly mentioned end-point of the known range, explicitly mentioned intermediate values or a specific example of the prior art in the overlap. It is not sufficient to exclude specific novelty destroying values known from the prior art range, it must also be considered whether the skilled person, in the light of the technical facts and taking into account the general knowledge in the field to be expected from him, would seriously contemplate applying the technical teaching of the prior art document in the range of overlap. If it can be fairly assumed that he would do so, it must be concluded that no novelty exists. In T 26/85, the skilled person could not seriously contemplate working in the area of overlap, since the prior art surprisingly contained a reasoned statement clearly dissuading him from choosing said range, although the latter was claimed in said prior art. The criteria mentioned in (ii) above can be applied analogously for assessing the novelty of overlapping numerical ranges (see T 17/85). As far as overlapping chemical formulae are concerned, novelty is acknowledged if the claimed subject-matter is distinguished from the prior art in the range of overlap by a new technical element (new technical teaching), see T 12/90, point 2.6 of the reasons, for example a specifically

selected chemical residue which is covered in general terms by the prior art in the overlapping area, but which is not individualised in the prior art document. If this is not the case, then it must be considered whether the skilled person would seriously contemplate working in the range of overlap and/or would accept that the area of overlap is directly and unambiguously disclosed in an implicit manner in the prior art (see for example T 536/95). If the answer is yes, then novelty is lacking.

8.1 Error margins in numerical values

The skilled person knows that numerical values relating to measurements are subject to measurement errors which place limits on their accuracy. For this reason, the general convention in the scientific and technical literature is applied: the last decimal place of a numerical value indicates its degree of accuracy. Where no other error margins are given, the maximum margin should be ascertained by applying the rounding-off convention to the last decimal place (see T 175/97), e.g. for a measurement of 3.5 cm, the error margin is 3.45-3.54. When interpreting ranges of values in patent specifications, the skilled person proceeds on the same basis.

9. Novelty of "reach-through" claims

"Reach-through" claims are defined as claims attempting to obtain protection for a chemical product (and also uses thereof, compositions thereof, etc.) by defining that product functionally in terms of its action (e.g. agonist, antagonist) on a biological target such as an enzyme or receptor (see F-III, 9). In many such cases, the applicant functionally defines chemical compounds in this way by reference to a newly identified biological target. However, compounds which bind to and exercise this action on that biological target are not necessarily novel compounds simply because the biological target which they act on is new. Indeed in many cases, the applicant himself provides test results in the application whereby known compounds are shown to exert this action on the new biological target, thus demonstrating that compounds falling within the functional definition of the "reach-through" claim are known in the state of the art and so establishing that a reach-through claim relating to compounds defined in this way lacks novelty.

Chapter VII – Inventive step

1. General

Art. 56

An invention is 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. Novelty (see G-IV, 5) and inventive step are different criteria. The question – "is there inventive step?" – only arises if the invention is novel.

2. State of the art; date of filing

The "state of the art" for the purposes of considering inventive step is as defined in Art. 54(2) (see G-IV, 1). It is to be understood as concerning such kind of information as is relevant to some field of technology (see T 172/03). It does not include later published European applications referred to in Art. 54(3). As mentioned in G-IV, 3, "date of filing" in Art. 54(2), means date of priority where appropriate (see F-VI). The state of the art may reside in the relevant common general knowledge, which need not necessarily be in writing and needs substantiation only if challenged (see T 939/92).

3. Person skilled in the art

The "person skilled in the art" should be presumed to be a skilled practitioner in the relevant field of technology, who is possessed of average knowledge and ability and is aware of what was common general knowledge in the art at the relevant date (see T 4/98, T 143/94 and T 426/88). He should also be presumed to have had access to everything in the "state of the art", in particular the documents cited in the search report, and to have had at his disposal the means and capacity for routine work and experimentation which are normal for the field of technology in question. If the problem prompts the person skilled in the art to seek its solution in another technical field, the specialist in that field is the person qualified to solve the problem. The skilled person is involved in constant development in his technical field (see T 774/89 and T 817/95). He may be expected to look for suggestions in neighbouring and general technical fields (see T 176/84 and T 195/84) or even in remote technical fields, if prompted to do so (see T 560/89). Assessment of whether the solution involves an inventive step must therefore be based on that specialist's knowledge and ability (see T 32/81). There may be instances where it is more appropriate to think in terms of a group of persons, e.g. a research or production team, rather than a single person (see T 164/92 and T 986/96). It should be borne in mind that the skilled person has the same level of skill for assessing inventive step and sufficient disclosure (see T 60/89, T 694/92 and T 373/94).

3.1 Common general knowledge of the skilled person

Common general knowledge can come from various sources and does not necessarily depend on the publication of a specific document on a specific date. An assertion that something is common general knowledge need only be backed by documentary evidence (for example, a textbook) if this is contested (see G-IV, 2).

A single publication (e.g. a patent document, but also the content of a technical journal) cannot normally be considered as common general knowledge (see T 475/88). In special cases, articles in technical journals can be representative of common general knowledge (see T 595/90). This applies in particular to articles providing a broad review or survey of a topic (see T 309/88). For the skilled person addressing the problem of bringing together certain starting materials, the conclusions of research on these materials carried out by only a very few manufacturers form part of the relevant general technical knowledge, even if the studies in question have only been published in technical journals (see T 676/94). Another exception is that it can also be the information contained in patent specifications or scientific publications, if the invention lies in a field of research which is so new that the relevant technical knowledge is not yet available from textbooks (see T 51/87).

Basic textbooks and monographs can be considered as representing common general knowledge (see T 171/84); if they contain references which direct the reader to further articles dealing with specific problems, these articles too may be counted as part of such knowledge (see T 206/83). Here it should be remembered that information does not become common general knowledge because it has been published in a particular textbook, reference work, etc.; on the contrary, it appears in books of this kind because it is already common general knowledge (see T 766/91). This means that the information in such a publication must have already become part of common general knowledge some time before the date of publication.

4. Obviousness

Thus the question to consider, in relation to any claim defining the invention, is whether before the filing or priority date valid for that claim, having regard to the art known at the time, it would have been obvious to the person skilled in the art to arrive at something falling within the terms of the claim. If so, the claim is not allowable for lack of inventive step. The term "obvious" means that which does not go beyond the normal progress of technology but merely follows plainly or logically from the prior art, i.e. something which does not involve the exercise of any skill or ability beyond that to be expected of the person skilled in the art. In considering inventive step, as distinct from novelty (see G-VI, 3), it is fair to construe any published document in the light of knowledge up to and including the day before the filing or priority date valid for the claimed invention and to have regard to all the knowledge generally available to the person skilled in the art up to and including that day.

5. Problem-and-solution approach

In order to assess inventive step in an objective and predictable manner, the so-called "**problem-and-solution approach**" should be applied. Thus deviation from this approach should be exceptional.

In the problem-and-solution approach, there are three main stages:

(i) determining the "closest prior art",

(ii) establishing the "objective technical problem" to be solved, and

(iii) considering whether or not the claimed invention, starting from the closest prior art and the objective technical problem, would have been obvious to the skilled person.

5.1 Determination of the closest prior art

The closest prior art is that which in one single reference discloses the combination of features which constitutes the most promising starting point for a development leading to the invention. In selecting the closest prior art, the first consideration is that it should be directed to a similar purpose or effect as the invention or at least belong to the same or a closely related technical field as the claimed invention. In practice, the closest prior art is generally that which corresponds to a similar use and requires the minimum of structural and functional modifications to arrive at the claimed invention (see T 606/89).

In some cases there are several equally valid starting points for the assessment of inventive step, e.g. if the skilled person has a choice of several workable solutions, i.e. solutions starting from different documents, which might lead to the invention. If a patent is to be granted, it may be necessary to apply the problem-and-solution approach to each of these starting points in turn, i.e. in respect of all these workable solutions. In the event of refusal, however, it is sufficient to show, on the basis of one relevant piece of prior art in respect of at least one of these solutions, that the claimed subject-matter lacks an inventive step. In such a situation, there is no need to discuss which document is "closest" to the invention; the only relevant question is whether the document used is a feasible starting point for assessing inventive step (see T 967/97, T 558/00, T 21/08, T 308/09 and T 1289/09). This is valid even if the problem identified in a problem-solution reasoning may be different from the one identified by the applicant/patentee.

The closest prior art must be assessed from the skilled person's point of view on the day before the filing or priority date valid for the claimed invention.

In identifying the closest prior art, account should be taken of what the applicant himself acknowledges in his description and claims to be known. Any such acknowledgement of known art should be regarded

by the examiner as being correct, unless the applicant states he has made a mistake (see C-IV, 7.2(vii)).

5.2 Formulation of the objective technical problem

In the second stage, one establishes in an objective way the **technical problem** to be solved. To do this one studies the application (or the patent), the closest prior art and the difference (also called "the **distinguishing feature(s)**" of the claimed invention) in terms of features (either structural or functional) between the claimed invention and the closest prior art, identifies the technical effect resulting from the distinguishing features, and then formulates the technical problem.

Features which cannot be seen to make any contribution, either independently or in combination with other features, to the technical character of an invention are not relevant for assessing inventive step (see T 641/00). Such a situation can occur for instance if a feature only contributes to the solution of a non-technical problem, for instance a problem in a field excluded from patentability (see T 931/95). For the treatment of claims comprising technical and non-technical aspects see G-VII, 5.4.

In the context of the problem-and-solution approach, 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 technical problem thus defined is often referred to as the "**objective technical problem**".

The objective technical problem derived in this way may not be what the applicant presented as "the problem" in his application. The latter may require reformulation, since the objective technical problem is based on objectively established facts, in particular appearing in the prior art revealed in the course of the proceedings, which may be different from the prior art of which the applicant was actually aware at the time the application was filed. In particular, the prior art cited in the search report may put the invention in an entirely different perspective from that apparent from reading the application only. Reformulation might lead to the objective technical problem being less ambitious than originally envisaged by the application. An example of such a case would be where the originally stated problem is the provision of a product, process or method demonstrating some improvement, but where there is no evidence that the claimed subject-matter is thereby improved over the closest prior art uncovered in the search; rather, there is only evidence with respect to more distantly related prior art (or possibly none at all). In this case, the problem has to be reformulated as the provision of an alternative product, process or method. The obviousness of the claimed solution to that reformulated problem must then be assessed in the light of the cited prior art (see T 87/08).

The extent to which such reformulation of the technical problem is possible has to be assessed on the merits of each particular case. As a matter of principle any effect provided by the invention may be used as

a basis for the reformulation of the technical problem, as long as said effect is derivable from the application as filed (see T 386/89). It is also possible to rely on new effects submitted subsequently during the proceedings by the applicant, provided that the skilled person would recognise these effects as implied by or related to the technical problem initially suggested (see G-VII, 11 and T 184/82).

It is noted that the objective technical problem must be so formulated as not to contain pointers to the technical solution, since including part of a technical solution offered by an invention in the statement of the problem must, when the state of the art is assessed in terms of that problem, necessarily result in an *ex post facto* view being taken of inventive activity (see T 229/85). Where the claim refers to an aim to be achieved in a non-technical field, however, this aim may legitimately appear in the formulation of the problem as part of the framework of the technical problem to be solved, in particular as a constraint that has to be met (see T 641/00, T 172/03 and G-VII, 5.4.1).

The expression "technical problem" should be interpreted broadly; it does not necessarily imply that the technical solution is an improvement to the prior art. Thus the problem could be simply to seek an alternative to a known device or process which provides the same or similar effects or is more cost-effective. A technical problem may be regarded as being solved only if it is credible that substantially all claimed embodiments exhibit the technical effects upon which the invention is based. Criteria for deciding whether lack of reproducibility of the claimed invention should be treated under Art. 56 or 83 are explained in F-III, 12.

Sometimes, the objective technical problem must be regarded as an aggregation of a plurality of "**partial problems**". This is the case where there is no technical effect achieved by all the distinguishing features taken in combination, but rather a plurality of partial problems is independently solved by different sets of distinguishing features (see G-VII, 6 and T 389/86).

5.3 Could-would approach

In the third stage the question to be answered is whether there is any teaching in the prior art as a whole that **would** (not simply could, but would) have prompted the skilled person, faced with the objective technical problem, to modify or adapt the closest prior art while taking account of that teaching, thereby arriving at something falling within the terms of the claims, and thus achieving what the invention achieves (see G-VII, 4).

In other words, the point is not whether the skilled person could have arrived at the invention by adapting or modifying the closest prior art, but whether he **would have done** so because the prior art incited him to do so in the hope of solving the objective technical problem or in expectation of some improvement or advantage (see T 2/83). Even an implicit prompting or implicitly recognisable incentive is sufficient to

show that the skilled person would have combined the elements from the prior art (see T 257/98 and T 35/04). This must have been the case for the skilled person before the filing or priority date valid for the claim under examination.

When an invention requires various steps to arrive at the complete solution of the technical problem, it should nevertheless be regarded as obvious if the technical problem to be solved leads the skilled person to the solution in a step-by-step manner and each individual step is obvious in the light of what has already been accomplished and of the residual task still to be solved (see T 623/97 and T 558/00).

5.4 Claims comprising technical and non-technical aspects

It is legitimate to have a mix of technical and "non-technical" features appearing in a claim, and the non-technical features may even form a major part of the claimed subject-matter.

Inventive step, however, can be based only on technical features, which thus have to be clearly defined in the claim. Non-technical features, to the extent that they do not interact with the technical subject-matter of the claim for solving a technical problem, i.e. non-technical features "as such", do not provide a technical contribution to the prior art and are thus ignored in assessing inventive step.

The problem-solution approach is in principle applied as follows to this type of claim, in particular for computer-implemented inventions:

(i) The non-technical aspects of the claim(s) are identified; a requirements specification (see G-VII, 5.4.1) is derived from the non-technical aspect(s) set out in the claims and the description so that the person skilled in the art of a technical field (e.g. an expert in computer science) is informed of the non-technical concept.

(ii) The closest prior art is selected on the basis of the technical aspects of the claimed subject-matter and the related description, also taking into account the considerations defined in G-VII, 5.1.

(iii) The differences from the closest prior art are identified.

  (a) If there are none (not even non-technical differences), an objection under Art. 54 is raised.

  (b) If the differences are not technical, an objection under Art. 56 is raised. The reasoning for the objection should be that the subject-matter of a claim cannot be inventive if there is no technical contribution to the art, i.e. if there is no technical problem solved by the claimed subject-matter vis-à-vis the closest prior art.

(c) If the differences include technical aspects, the following applies: firstly, the objective technical problem is formulated, taking into account the requirements specification as under point (i) above; the solution of the objective technical problem must comprise the technical aspects of the identified differences; secondly, if the solution of the technical problem is obvious to the person skilled in the art, an objection under Art. 56 is raised.

Care should be taken to avoid missing any features that might contribute to the technical character of the claimed subject-matter, in particular when the wording of the claim is paraphrased for the purpose of analysis (T 756/06).

5.4.1 "Requirements specification" in the formulation of the objective technical problem

Features which do not contribute to the technical character or do not make any contribution, either independently or in combination with other features, to the technical solution of a technical problem are not relevant for assessing inventive step (see T 641/00). Such a situation may arise, for instance, if a feature contributes only to the solution of a non-technical problem, e.g. a problem in a field excluded from patentability.

Where aspects of a claim define an aim to be achieved in a non-technical field and thus do not contribute to the technical character of the invention, this aim may legitimately appear in the formulation of the objective technical problem in the form of a "requirements specification" (i.e. a complete description of the behaviour of the system to be developed) provided to the person skilled in a technical field as part of the framework of the technical problem that is to be solved, in particular as a constraint that has to be met. If no such objective technical problem is found, the claimed subject-matter does not satisfy at least the requirement for an inventive step because there can be no technical contribution to the art, and the claim is to be rejected on this ground.

The objective technical problem must be so formulated as not to contain pointers to the technical solution, since including part of a technical solution offered by an invention in the statement of the problem must, when the state of the art is assessed in terms of that problem, necessarily result in an *ex post facto* view being taken of inventive activity. The requirements specification is not deemed to belong to the prior art; it is merely used in the formulation of the technical problem.

6. Combining pieces of prior art

In the context of the problem-solution approach, it is permissible to combine the disclosure of one or more documents, parts of documents or other pieces of prior art (e.g. a public prior use or unwritten general technical knowledge) with the closest prior art. However, the fact that

more than one disclosure must be combined with the closest prior art in order to arrive at a combination of features may be an indication of the presence of an inventive step, e.g. if the claimed invention is not a mere aggregation of features (see G-VII, 7).

A different situation occurs where the invention is a solution to a plurality of independent "partial problems" (see G-VII, 7 and 5.2). Indeed, in such a case it is necessary to separately assess, for each partial problem, whether the combination of features solving the partial problem is obviously derivable from the prior art. Hence, a different document can be combined with the closest prior art for each partial problem (see T 389/86). For the subject-matter of the claim to be inventive, it suffices however that one of these combinations of features involves an inventive step.

In determining whether it would be obvious to combine two or more distinct disclosures, the examiner should also have regard in particular to the following:

(i) whether the content of the disclosures (e.g. documents) is such as to make it likely or unlikely that the person skilled in the art, when faced with the problem solved by the invention, would combine them - for example, if two disclosures considered as a whole could not in practice be readily combined because of inherent incompatibility in disclosed features essential to the invention, the combining of these disclosures should not normally be regarded as obvious;

(ii) whether the disclosures, e.g. documents, come from similar, neighbouring or remote technical fields (see G-VII, 3);

(iii) the combining of two or more parts of the same disclosure would be obvious if there is a reasonable basis for the skilled person to associate these parts with one another. It would normally be obvious to combine with a prior-art document a well-known textbook or standard dictionary; this is only a special case of the general proposition that it is obvious to combine the teaching of one or more documents with the **common general knowledge** in the art. It would, generally speaking, also be obvious to combine two documents one of which contains a clear and unmistakable reference to the other (for references which are considered an integral part of the disclosure, see G-IV, 5.1 and G-VI, 1). In determining whether it is permissible to combine a document with an item of prior art made public in some other way, e.g. by use, similar considerations apply.

7. Combination vs. juxtaposition or aggregation

The invention claimed must normally be considered as a whole. When a claim consists of a "combination of features", it is not correct to argue that the separate features of the combination taken by themselves are

known or obvious and that "therefore" the whole subject-matter claimed is obvious. However, where the claim is merely an "aggregation or juxtaposition of features" and not a true combination, it is enough to show that the individual features are obvious to prove that the aggregation of features does not involve an inventive step (see G-VII, 5.2, last paragraph). A set of technical features is regarded as a combination of features if the functional interaction between the features achieves a combined technical effect which is different from, e.g. greater than, the sum of the technical effects of the individual features. In other words, the interactions of the individual features must produce a synergistic effect. If no such synergistic effect exists, there is no more than a mere aggregation of features (see T 389/86, and T 204/06).

For example, the technical effect of an individual transistor is essentially that of an electronic switch. However, transistors interconnected to form a microprocessor synergically interact to achieve technical effects, such as data processing, which are over and above the sum of their respective individual technical effects (see also G-VII, Annex, 2).

According to T 9/81, patentability has been accepted for a preparation in the form of a “kit-of-parts” in which the individual active compounds, representing known therapeutic agents, are physically separated, provided that the use of those compounds, either simultaneously, separately or sequentially, produces a new and unexpected joint therapeutic effect which cannot be attained by the compounds independently of each other.

8. "*Ex post facto*" analysis

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, been 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 seek to make a "real-life" assessment of this and other relevant factors. He should take into account all that is known concerning the background of the invention and give fair weight to relevant arguments or evidence submitted by the applicant. If, for example, an invention is shown to be of considerable technical value, and particularly if it provides a technical advantage which is new and surprising and which is not merely achieved as a bonus effect in a "one-way street" situation (see G-VII, 10.2), and this technical advantage can convincingly be related to one or more of the features included in the claim defining the

invention, the examiner should be hesitant in pursuing an objection that such a claim lacks inventive step.

9. Origin of an invention

While the claim should in each case be directed to technical features (and not, for example, merely to an idea), in order to assess whether an inventive step is present it is important for the examiner to bear in mind that an invention may, for example, be based on the following:

(i) the devising of a solution to a known problem;

Example: the problem of permanently marking farm animals such as cows without causing pain to the animals or damage to the hide has existed since farming began. The solution ("freeze-branding") consists in applying the discovery that the hide can be permanently depigmented by freezing.

(ii) the arrival at an insight into the cause of an observed phenomenon (the practical use of this phenomenon then being obvious);

Example: the agreeable flavour of butter is found to be caused by minute quantities of a particular compound. As soon as this insight has been arrived at, the technical application comprising adding this compound to margarine is immediately obvious.

Many inventions are of course based on a combination of the above possibilities - e.g. the arrival at an insight and the technical application of that insight may both involve the use of the inventive faculty.

10. Secondary indicators

10.1 Predictable disadvantage; non-functional modification; arbitrary choice

It should be noted that if the invention is the result of a foreseeable disadvantageous modification of the closest prior art, which the skilled person could clearly predict and correctly assess, and if this predictable disadvantage is not accompanied by an unexpected technical advantage, then the claimed invention does not involve an inventive step (see T 119/82 and T 155/85). In other words, a mere foreseeable worsening of the prior art does not involve an inventive step. However, if this worsening is accompanied by an unexpected technical advantage, an inventive step might be present. Similar considerations apply to the case where an invention is merely the result of an arbitrary non-functional modification of a prior-art device or of a mere arbitrary choice from a host of possible solutions (see T 72/95 and T 939/92).

10.2 Unexpected technical effect; bonus effect

An unexpected technical effect may be regarded as an indication of inventive step. It must, however, derive from the subject-matter as claimed, not merely from some additional features which are mentioned only in the description. However, if, having regard to the state of the art, it would already have been obvious for a skilled person to arrive at something falling within the terms of a claim, for example due to a lack of alternatives thereby creating a "one-way street" situation, the unexpected effect is merely a bonus effect which does not confer inventiveness on the claimed subject-matter (see T 231/97 and T 192/82).

10.3 Long-felt need; commercial success

Where the invention 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, this may be regarded as an indication of inventive step.

Commercial success alone is not to be regarded as indicative of inventive step, but evidence of immediate commercial success when coupled with evidence of a long-felt want is of relevance provided the examiner is satisfied that the success derives from the technical features of the invention and not from other influences (e.g. selling techniques or advertising).

11. Arguments and evidence submitted by the applicant

The relevant arguments and evidence to be considered by the examiner for assessing inventive step may either be taken from the originally-filed patent application or submitted by the applicant during the subsequent proceedings (see G-VII, 5.2, and H-V, 2.2 and 2.4).

Care must be taken, however, whenever new effects in support of inventive step are referred to. Such new effects can only be taken into account if they are implied by or at least related to the technical problem initially suggested in the originally filed application (see also G-VII, 5.2, T 386/89 and T 184/82).

Example of such a new effect:

The invention as filed relates to a pharmaceutical composition having a specific activity. At first sight, having regard to the relevant prior art, it would appear that there is a lack of inventive step. Subsequently, the applicant submits new evidence which shows that the claimed composition exhibits an unexpected advantage in terms of low toxicity. In this case, it is allowable to reformulate the technical problem by including the aspect of toxicity, since pharmaceutical activity and toxicity are related in the sense that the skilled person would always contemplate the two aspects together.

The reformulation of the technical problem may or may not give rise to amendment or insertion of the statement of the technical problem in the description. Any such amendment is only allowable if it satisfies the

conditions listed in H-V, 2.4. In the above example of a pharmaceutical composition, neither the reformulated problem nor the information on toxicity could be introduced into the description without infringing Art. 123(2).

12. Selection inventions

The subject-matter of selection inventions differs from the closest prior art in that it represents selected sub-sets or sub-ranges. If this selection is connected to a particular technical effect, and if no hints exist leading the skilled person to the selection, then an inventive step is accepted (this technical effect occurring within the selected range may also be the same effect as attained with the broader known range, but to an unexpected degree). The criterion of "seriously contemplating" mentioned in connection with the test for novelty of overlapping ranges should not be confused with the assessment of inventive step. For inventive step, it has to be considered whether the skilled person would have made the selection or would have chosen the overlapping range in the hope of solving the underlying technical problem or in expectation of some improvement or advantage. If the answer is negative, then the claimed matter involves an inventive step.

The unexpected technical effect must apply to the entire range as claimed. If it occurs in only part of the claimed range, the claimed subject-matter does not solve the specific problem to which the effect relates, but only the more general problem of obtaining, for example, "a further product X" or "a further process Y" (see T 939/92).

13. Dependent claims; claims in different categories

If the subject-matter of an independent claim is new and non-obvious, there is no need to investigate the novelty and non-obviousness of the subject-matter of any claims dependent thereon, except in situations where the subject-matter of a dependent claim has a later effective date than the independent claim and intermediate documents are to be considered (see F-VI, 2.4.3).

Similarly, if the subject-matter of a claim to a product is new and non-obvious there is no need to investigate the novelty and non-obviousness of the subject-matter of any claims for a process which inevitably results in the manufacture of that product or of any claims for a use of that product. In particular, analogy processes, i.e. processes which themselves would otherwise not involve an inventive step, are nevertheless patentable insofar as they provide a novel and inventive product (see T 119/82). It should, however, be noted that in cases where the product, process and use claims have different effective dates, a separate examination as to novelty and inventive step may still be necessary in view of intermediate documents.

14. Examples

The annex to this chapter gives examples of circumstances where an invention may be regarded as obvious or where it may involve an inventive step. It is to be stressed that these examples are only for illustrative purposes and that the applicable principle in each case is "was it obvious to a person skilled in the art?" (see G-VII, 5). Examiners should avoid attempts to fit a particular case into one of these examples if it is not clearly applicable. Also, the list is not exhaustive.

Annex
Examples relating to the requirement of inventive step – indicators

1. Application of known measures?

1.1 Inventions involving the application of **known measures** in an obvious way and in respect of which an inventive step is therefore to be ruled out:

(i) The teaching of a prior document is incomplete and at least one of the possible ways of "**filling the gap**" which would naturally or readily occur to the skilled person results in the invention.

Example: The invention relates to a building structure made from aluminium. A prior document discloses the same structure and says that it is of light-weight material but fails to mention the use of aluminium.

(ii) The invention differs from the known art merely in the use of **well-known equivalents** (mechanical, electrical or chemical).

Example: The invention relates to a pump which differs from a known pump solely in that its motive power is provided by a hydraulic motor instead of an electric motor.

(iii) The invention consists merely in a new use of a well-known material employing the **known properties** of that material.

Example: Washing composition containing as detergent a known compound having the known property of lowering the surface tension of water, this property being known to be an essential one for detergents.

(iv) The invention consists in the substitution in a known device of a recently developed material whose properties make it plainly suitable for that use ("**analogous substitution**").

Example: An electric cable comprises a polyethylene sheath bonded to a metallic shield by an adhesive. The invention lies in the use of a particular newly developed adhesive known to be suitable for polymer-metal bonding.

(v) The invention consists merely in the use of a known technique in a closely analogous situation ("**analogous use**").

Example: The invention resides in the application of a pulse control technique to the electric motor driving the auxiliary mechanisms of an industrial truck, such as a fork-lift truck, the use of this technique to control the electric propulsion motor of the truck being already known.

1.2 Inventions involving the application of **known measures** in a **non-obvious** way and in respect of which an inventive step is therefore to be recognised:

(i) A known working method or means when used for a **different purpose** involves a new, **surprising effect.**

Example: It is known that high-frequency power can be used in **in**ductive butt welding. It should therefore be obvious that high-frequency power could also be used in **con**ductive butt welding with similar effect. However, if high-frequency power were used for the continuous conductive butt welding of coiled strip but without removing scale (such scale removal normally being necessary during conductive welding in order to avoid arcing between the welding contact and the strip), there is the unexpected additional effect that scale removal is found to be unnecessary because at high frequency the current is supplied in a predominantly capacitive manner via the scale which forms a dielectric. In that case, an inventive step would exist.

(ii) A new use of a known device or material involves **overcoming technical difficulties** not resolvable by routine techniques.

Example: The invention relates to a device for supporting and controlling the rise and fall of gas holders, enabling the previously employed external guiding framework to be dispensed with. A similar device was known for supporting floating docks or pontoons but practical difficulties not encountered in the known applications needed to be overcome in applying the device to a gas holder.

2. Obvious combination of features?

2.1 Obvious and consequently **non-inventive combination** of features:

The invention consists merely in the **juxtaposition** or association of known devices or processes functioning in their normal way and not producing any non-obvious working inter-relationship.

Example: Machine for producing sausages consists of a known mincing machine and a known filling machine disposed side by side.

2.2 Not obvious and consequently **inventive combination** of features:

The combined features mutually support each other in their effects to such an extent that a new technical result is achieved. It is irrelevant whether each individual feature is fully or partly known by itself. However, if the combination of features is a bonus effect, e.g. as the result of a "one-way street" situation, the combination might lack an inventive step.

Example: A mixture of medicines consists of a painkiller (analgesic) and a tranquilliser (sedative). It was found that through the addition of the tranquilliser, which intrinsically appeared to have no painkilling effect, the analgesic effect of the painkiller was intensified in a way which could not have been predicted from the known properties of the active substances.

3. Obvious selection?

3.1 Obvious and consequently **non-inventive selection** among a number of known possibilities:

(i) The invention consists merely in choosing from a number of **equally likely alternatives**.

Example: The invention relates to a known chemical process in which it is known to supply heat electrically to the reaction mixture. There are a number of well-known alternative ways of so supplying the heat, and the invention resides merely in the choice of one alternative.

(ii) The invention resides in the choice of particular dimensions, temperature ranges or other parameters from a limited range of possibilities, and it is clear that these parameters could be arrived at by routine trial and error or by the application of **normal design procedures**.

Example: The invention relates to a process for carrying out a known reaction and is characterised by a specified rate of flow of an inert gas. The prescribed rates are merely those which would necessarily be arrived at by the skilled practitioner.

(iii) The invention can be arrived at merely by a **simple extrapolation** in a straightforward way from the known art.

Example: The invention is characterised by the use of a specified minimum content of a substance X in a preparation Y in order to improve its thermal stability, and this characterising feature can be derived merely by extrapolation on a straight-line graph, obtainable from the known art, relating thermal stability to the content of substance X.

(iv) The invention consists merely in **selecting** particular chemical compounds or compositions (including alloys) **from a broad field**.

Example: The prior art includes disclosure of a chemical compound characterised by a specified structure including a substituent group designated "R". This substituent "R" is defined so as to embrace entire ranges of broadly-defined radical groups such as all alkyl or aryl radicals either unsubstituted or

substituted by halogen and/or hydroxy, although for practical reasons only a very small number of specific examples are given. The invention consists in the selection of a particular radical or particular group of radicals from amongst those referred to as the substituent "R" (the selected radical or group of radicals not being specifically disclosed in the prior-art document since the question would then be one of lack of novelty rather than obviousness). The resulting compounds:

(a) are neither described as having nor shown to possess any advantageous properties not possessed by the prior art examples; or

(b) are described as possessing advantageous properties compared with the compounds specifically referred to in the prior art, but these properties are ones which the person skilled in the art would expect such compounds to possess, so that he is likely to be led to make this selection.

(v) The invention follows inevitably from developments in the prior art, in such a way that there was no choice between several possibilities (the "**one-way street**" situation).

Example: From the prior art it is known that when you reach a particular compound in a series of known chemical compounds, expressed in terms of the number of carbon atoms, there is a consistently increasing insecticidal effect as you move up the series. With regard to insecticidal effect, the next member of the series after the member previously known then lies in a "one-way street". If this member of the series, in addition to exhibiting the expected enhanced insecticidal effect, proves also to have the unexpected effect of being selective, i.e. of killing some insects but not others, it nevertheless remains obvious.

3.2 Not obvious and consequently **inventive selection** among a number of known possibilities:

(i) The invention involves **special selection** in a process of particular operating conditions (e.g. temperature and pressure) within a known range, such selection producing **unexpected effects** in the operation of the process or the properties of the resulting product.

Example: In a process where substance A and substance B are transformed at high temperature into substance C, it was known that there is in general a constantly increased yield of substance C as the temperature increases in the range between 50 and 130 °C. It is now found that in the temperature range from 63 to 65 °C, which previously had not been explored, the yield of substance C was considerably higher than expected.

(ii) The invention consists in selecting **particular** chemical compounds or compositions (including alloys) from a broad field, such compounds or compositions having **unexpected advantages**.

Example: In the example of a substituted chemical compound given at G-VII, Annex, 3.1(iv) above, the invention again resides in the selection of the substituent radical "R" from the total field of possibilities defined in the prior disclosure. In this case, however, not only does the selection embrace a particular area of the possible field, and result in compounds that can be shown to possess advantageous properties (see G-VII, 10 and H-V, 2.2) but there are no indications which would lead the person skilled in the art to this particular selection rather than any other in order to achieve the advantageous properties.

4. Overcoming a technical prejudice?

As a general rule, there is an inventive step if the prior art leads the person skilled in the art away from the procedure proposed by the invention. This applies in particular when the skilled person would not even consider carrying out experiments to determine whether these were alternatives to the known way of overcoming a real or imagined technical obstacle.

Example: Drinks containing carbon dioxide are, after being sterilised, bottled while hot in sterilised bottles. The general opinion is that immediately after withdrawal of the bottle from the filling device the bottled drink must be automatically shielded from the outside air so as to prevent the bottled drink from spurting out. A process involving the same steps but in which no precautions are taken to shield the drink from the outside air (because none are in fact necessary) would therefore be inventive.