Part G
Patentability

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Chapter I – Patentability

1. Patentability requirements

There are four basic requirements for patentability:
(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 of an invention

In addition to these four requirements, an invention must fulfil the following:
(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
(ii) the invention must be of "technical character" to the extent that it must relate to a technical field (Rule 42(1)(a) – see F-II, 4.2), must be concerned with a technical problem (Rule 42(1)(c) – see F-II, 4.5) 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).

3. Technical progress, advantageous effect

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, an advantageous effect, if any, with respect to the state of the art should be stated in the description (Rule 42(1)(c)), as any such effect is often important in determining "inventive step" (see G-VII, 5).

Art. 52(1)
Art. 83
Rule 42(1)(a) and (c)
Rule 43(1)

Chapter II – Inventions

1. General remarks

The EPC does not define what is meant by "invention", but Art. 52(2) contains a non-exhaustive list of "non-inventions", i.e. subject-matter which is not to be regarded as an invention within the meaning of Art. 52(1). 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 have a technical character (see G-I, 2(ii)). It may be in any field of technology.

2. Examination practice

The question of whether there is an invention within the meaning of Art. 52(1) is separate and distinct from the questions of whether it is susceptible of industrial application, is new and involves an inventive step. The exclusions from patentability under Art. 52(2) play a role in assessing both patent eligibility and inventive step because patent protection is reserved for inventions involving a "technical teaching", i.e. an instruction addressed to a skilled person as to how to solve a particular technical problem using particular technical means. This twofold assessment is referred to as the "two-hurdle approach" (G 1/19).

The first hurdle, also referred to as the patent eligibility hurdle, requires that the claimed subject-matter as a whole must not fall under the "non-inventions" defined in Art. 52(2) and (3). The exclusion from patentability of the subject-matters and activities referred to in Art. 52(2) is limited by Art. 52(3) to such subject-matters or activities that are claimed "as such". This limitation is a bar to a broad interpretation of the non-inventions. It implies that one technical feature is sufficient for eligibility: If the claimed subject-matter is directed to or uses technical means, it is an invention within the meaning of Art. 52(1). This assessment is made without reference to the prior art.

The second hurdle is where inventive step is assessed. In addition to technical features, claims may also comprise non-technical features. In this context, the term "non-technical features" refers to features which, on their own, would be considered "non-inventions" under Art. 52(2). Inventive step of claims comprising such a mix of technical and non-technical features is assessed using the COMVIK approach (G-VII, 5.4). This approach is a special application of the problem-solution approach that involves establishing which features of the invention contribute to its technical character (i.e. contribute to the technical solution of a technical problem by providing a technical effect). A feature may support the presence of an inventive step if and to the extent that it contributes to the technical character of the invention. Whether any feature contributes to the technical character of the invention has to be assessed in the context of the invention as a whole.

Art. 52(2) and (3)

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

If a new property of a known material or article is found, 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

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

Mathematical methods play an important role in the solution of technical problems in all fields of technology. However, they are excluded from patentability under Art. 52(2)(a) when claimed as such (Art. 52(3)).

The exclusion applies if a claim is directed to a purely abstract mathematical method and the claim does not require any technical means. For instance, a method for performing a Fast Fourier Transform on **abstract data** which does not specify the use of any technical means is a mathematical method as such. A purely **abstract** mathematical object or concept, e.g. a particular type of geometric object or of graph with nodes and edges, is not a method but is nevertheless not an invention within the meaning of Art. 52(1) because it lacks a technical character.

If a claim is directed either to a method involving the use of technical means (e.g. a computer) or to a device, its subject-matter has a technical character as a whole and is thus not excluded from patentability under

Art. 52(2) and (3).
Art. 52(2)(a)
Art. 52(2)(a)
Art. 52(2)(a)
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Merely specifying the technical nature of the data or parameters of the mathematical method may not be sufficient on its own to define an invention within the meaning of Art. 52(1). Even if the resulting method would not be considered a purely abstract mathematical method as such within the meaning of Art. 52(2)(a) and (3), it may still fall under the excluded category of methods for performing mental acts as such if no use of technical means is implied (Art. 52(2)(c) and (3); see G-II, 3.5.1).
Once it is established that the claimed subject-matter as a whole is not excluded from patentability under Art. 52(2) and (3) and is thus an invention within the meaning of Art. 52(1), it is examined in respect of the other requirements of patentability, in particular novelty and inventive step (G-I, 1).
For the assessment of inventive step, all features which contribute to the technical character of the invention must be taken into account (G-VII, 5.4). When the claimed invention is based on a mathematical method, it is assessed whether the mathematical method contributes to the technical character of the invention.
A mathematical method may contribute to the technical character of an invention, i.e. contribute to producing a **technical effect** that serves a technical purpose, by its application to a field of technology and/or by being adapted to a specific technical implementation (T 2330/13). The criteria for assessing these two situations are explained below.
Technical applications
When assessing the contribution made by a mathematical method to the technical character of an invention, it must be taken into account whether the method, in the context of the invention, produces a technical effect serving a technical purpose.
Examples of technical contributions of a mathematical method are:
– controlling a specific technical system or process, e.g. an X-ray apparatus or a steel cooling process;
– determining from measurements a required number of passes of a compaction machine to achieve a desired material density;
– digital audio, image or video enhancement or analysis,
e.g. de-noising, detecting persons in a digital image, estimating the quality of a transmitted digital audio signal;
– separation of sources in speech signals; speech recognition,
e.g. mapping a speech input to a text output;
– encoding data for reliable and/or efficient transmission or storage (and corresponding decoding), e.g. error-correction coding of data for transmission over a noisy channel, compression of audio, image, video or sensor data;

– encrypting/decrypting or signing electronic communications;
generating keys in an RSA cryptographic system;
– optimising load distribution in a computer network;
– determining the energy expenditure of a subject by processing data obtained from physiological sensors; deriving the body temperature of a subject from data obtained from an ear temperature detector;
– providing a genotype estimate based on an analysis of DNA samples, as well as providing a confidence interval for this estimate so as to quantify its reliability;
– providing a medical diagnosis by an automated system processing physiological measurements.

A **generic** purpose such as "controlling a technical system" is not sufficient to confer a technical character to the mathematical method. The technical purpose must be a **specific** one.

Furthermore, the mere fact that a mathematical method may serve a technical purpose is not sufficient, either. The claim is to be functionally **limited** to the technical purpose, either explicitly or implicitly. This can be achieved by establishing a sufficient link between the technical purpose and the mathematical method steps, for example, by specifying how the input and the output of the sequence of mathematical steps relate to the technical purpose so that the mathematical method is causally linked to a technical effect.

Defining the nature of the data input to a mathematical method does not necessarily imply that the mathematical method contributes to the technical character of the invention (T 2035/11, T 1029/06, T 1161/04).

If steps of a mathematical method are used to derive or predict the physical state of an existing real object from measurements of physical properties, as in the case of indirect measurements, those steps make a technical contribution regardless of what use is made of the results.

Technical implementations

A mathematical method may also contribute to the technical character of the invention independently of any technical application when the claim is directed to a **specific technical implementation** of the mathematical method and the mathematical method is particularly **adapted** for that implementation in that its design is motivated by technical considerations of the **internal functioning** of the computer system or network (T 1358/09, G 1/19). This may happen if the mathematical method is designed to exploit particular technical properties of the technical system on which it is implemented to bring about a technical effect such as efficient use of computer storage capacity or network bandwidth. For instance, the adaptation of a polynomial reduction algorithm to exploit wordsize shifts matched to the word size of the computer hardware is based on such March 2022 Guidelines for Examination in the EPO Part G – Chapter II-5 technical considerations and can contribute to producing the technical effect of an efficient hardware implementation of said algorithm. Another

example is assigning the execution of data-intensive training steps of a machine-learning algorithm to a graphical processing unit (GPU) and preparatory steps to a standard central processing unit (CPU) to take advantage of the parallel architecture of the computing platform. The claim should be directed to the implementation of the steps on the GPU and CPU for this mathematical method to contribute to the technical character.

Computational efficiency

If the mathematical method does not serve a technical purpose and the claimed technical implementation does not go beyond a generic technical implementation, the mathematical method does not contribute to the technical character of the invention. In such a case, it is not sufficient that the mathematical method is algorithmically more efficient than prior-art mathematical methods to establish a technical effect (see also G-II, 3.6). However, if it is established that the mathematical method produces a technical effect due to having been applied to a field of technology and/or adapted to a specific technical implementation, the computational efficiency of the steps affecting that established technical effect is to be taken into account when assessing inventive step. See G-II, 3.6.4 for examples where an improvement in computational efficiency qualifies as a technical effect.

3.3.1 Artificial intelligence and machine learning

Artificial intelligence and machine learning are based on computational models and algorithms for classification, clustering, regression and dimensionality reduction, such as neural networks, genetic algorithms, support vector machines, k-means, kernel regression and discriminant analysis. Such computational models and algorithms are per se of an abstract mathematical nature, irrespective of whether they can be "trained" based on training data. Hence, the guidance provided in G-II, 3.3 generally applies also to such computational models and algorithms.

Terms such as "support vector machine", "reasoning engine" or "neural network" may, depending on the context, merely refer to abstract models or algorithms and thus do not, on their own, necessarily imply the use of a technical means. This has to be taken into account when examining whether the claimed subject-matter has a technical character as a whole (Art. 52(1), (2) and (3)).

Artificial intelligence and machine learning find applications in various fields of technology. For example, the use of a neural network in a heart monitoring apparatus for the purpose of identifying irregular heartbeats makes a technical contribution. The classification of digital images, videos, audio or speech signals based on low-level features (e.g. edges or pixel attributes for images) are further typical technical applications of classification algorithms. Further examples of technical purposes for which artificial intelligence and machine learning could be used may be found in the list under G-II, 3.3.

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Classifying text documents solely in respect of their textual content is however not regarded to be *per se* a technical purpose but a linguistic one

(T 1358/09). Classifying abstract data records or even "telecommunication network data records" without any indication of a technical use being made of the resulting classification is also not *per se* a technical purpose, even if the classification algorithm may be considered to have valuable mathematical properties such as robustness (T 1784/06).
Where a classification method serves a technical purpose, the steps of generating the training set and training the classifier may also contribute to the technical character of the invention if they support achieving that technical purpose.

3.3.2 Simulation, design or modelling

Claims directed to methods of simulation, design or modelling typically comprise features which fall under the category of mathematical methods or of methods for performing mental acts. Hence, the claimed subject-matter as a whole may fall under the exclusions from patentability mentioned under Art. 52(2)(a)(c) and (3) (see G-II, 3.3 and 3.5.1).
The methods considered in this section, however, are at least partially computer-implemented so that the claimed subject-matter as a whole is not excluded from patentability.
Computer-implemented methods of simulating, designing or modelling should be examined according to the same criteria as any other computerimplemented inventions (G-VII, 5.4, G 1/19).
For establishing the presence of a technical effect, it is not decisive whether the simulated system or process is technical or whether the simulation reflects technical principles underlying the simulated system and how accurately it does so.

Simulations interacting with the external physical reality

Computer-implemented simulations that comprise features representing an interaction with an external physical reality at the level of their input or output may provide a technical effect related to this interaction. A computerimplemented simulation that uses measurements as input may form part of an indirect measurement method that calculates or predicts the physical state of an existing real object and thus make a technical contribution regardless of what use is made of the results.

Purely numerical simulations

A computer-implemented simulation without an input or output having a direct link with physical reality may still solve a technical problem. In such a "purely numerical" simulation, the underlying models and algorithms may contribute to the technical character of the invention by their adaptation to a **specific technical implementation** or by an **intended technical use** of the **data resulting from the simulation**.
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Models and algorithms that do not make a contribution to the technical character of the invention form constraints that may be included in the formulation of the objective technical problem when following the COMVIK

approach outlined in G-VII, 5.4.

Specific technical implementation of a numerical simulation

The technical contribution that may be made by a model or algorithm because of their adaptation to the internal functioning of the computer system or network on which they are implemented is assessed in the same manner as adaptations of mathematical methods to specific technical implementations, see G-II, 3.3.

Intended technical use of the calculated numerical output data of a numerical simulation

Calculated numerical data reflecting the physical state or behaviour of a system or process existing only as a model in a computer usually cannot contribute to the technical character of the invention, even if it reflects the behaviour of the real system or process adequately.

Calculated numerical data may have a "**potential technical effect**", which is the technical effect that would be produced when the data is used according to an intended technical use. Such a potential technical effect may **only** be relied on for the formulation of the objective technical problem if the intended technical use is either explicitly or implicitly specified in the claim.

If the data resulting from a numerical simulation is **specifically adapted** for an intended technical use, e.g. it is control data for a technical device, a potential technical effect of the data can be considered "**implied**" by the claim. The specific adaptation implies that the claim does not encompass other non-technical uses because the intended technical use is then inherent to the claimed subject-matter over substantially the whole scope of the claim (see also G-II, 3.6.3). On the other hand, if the claim also encompasses non-technical uses of the simulation results (such as gaining scientific knowledge about a technical or natural system), the potential technical effect is not achieved over substantially the whole scope of the claim and therefore cannot be relied on in the assessment of inventive step.

Accuracy

Whether a simulation contributes to the technical character of the claimed subject-matter does not depend on the quality of the underlying model or the degree to which the simulation represents reality.

However, the accuracy of a simulation is a factor that may have an influence on an already established technical effect going beyond the mere implementation of the simulation on a computer. It may be that an alleged improvement is not achieved if the simulation is not accurate enough for its intended technical use. This may be taken into account in the formulation of the objective technical problem (Art. 56) or in the assessment of sufficiency of disclosure (Art. 83), see F-III, 12. Conversely, a technical effect may still

be achieved by a method where certain simulation parameters are inaccurate but sufficient for its intended technical use.

Design processes

The aforementioned principles apply equally if a computer-implemented

simulation is claimed as part of a design process.
If a computer-implemented method results merely in an abstract model of a product, system or process, e.g. a set of equations, this *per se* is not considered to be a technical effect, even if the modelled product, system or process is technical (T 49/99, T 42/09). For example, a logical data model for a family of product configurations has no inherent technical character, and a method merely specifying how to proceed to arrive at such a logical data model would not make a technical contribution beyond its computer-implementation. Likewise, a method merely specifying how to describe a multi-processor system in a graphical modelling environment does not make a technical contribution beyond its computer-implementation. Reference is made to G-II, 3.6.2 related to information modelling as an intellectual activity.

3.4 Aesthetic creations

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 letter font, would not be considered as technical features. Nor 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.
Art. 52(2)(b)

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.

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

3.5.1 Schemes, rules and methods for performing mental acts

The exclusion from patentability of schemes, rules and methods for performing mental acts under Art. 52(2)(c) concerns instructions to the human mind on how to conduct cognitive, conceptual or intellectual processes, for instance how to learn a language. The exclusion applies only when such schemes, rules and methods are claimed as such (Art. 52(3)).

If a method claim encompasses a purely mental realisation of all method steps, it falls under the category of methods for performing mental acts as such (Art. 52(2)(c) and (3)). This applies regardless of whether the claim encompasses also technical embodiments and of whether the method is based on technical considerations (T 914/02, T 471/05, G 3/08).

An example is a claim defining a method for designing an arrangement for loading nuclear reactor fuel bundles into a reactor core in order to maximise the amount of energy that is generated before the reactor fuel needs to be refreshed. The method involves determining optimal values for specific technical parameters of the arrangement by starting with initial values, performing simulations based on these values, and iteratively changing the values based on simulation results until a stopping criterion is met. Such a method is based on technical considerations related to the technical field of nuclear reactors. However, as long as the claim does not exclude that all method steps may be carried out mentally, the claimed subject-matter is excluded from patentability. This objection also applies when the simulation involves real world values obtained by a technical measurement, if the claim does not include either a step of carrying out the technical measurement or a step of receiving the measured real world values using technical means.

In general, the complexity of a method cannot disqualify it as a method for performing mental acts as such. If technical means (e.g. a computer) are necessary to carry out the method, they are included in the claim as an essential feature (Art. 84, F-IV, 4.5). See also G-II, 3.3 for aspects related to algorithmic efficiency.

Art. 52(2)(c)

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A claimed method is not a method for performing mental acts as such if it requires the use of technical means (e.g. a computer, a measuring device, etc.) to carry out at least one of its steps or if it provides a physical entity as

the resulting product (e.g. if it is a method of manufacturing a product comprising steps of designing the product and a step of manufacturing the product so designed).
Once it is established that the claimed method as a whole is not excluded from patentability under Art. 52(2) and (3), it is examined in respect of the other requirements of patentability, in particular novelty and inventive step (G-I, 1).
Where a claim defining a method for performing mental acts as such is limited by specifying that the method is carried out by a computer, not only the use of a computer but also the steps carried out by the computer themselves may make a technical contribution if they then contribute to a technical effect. The presence of technical considerations, such as those related to the technical field of nuclear reactors in the example above, is not in itself sufficient to acknowledge the presence of a technical effect (G 1/19).
A method comprising steps which involve the use of technical means may also specify steps which are to be carried out mentally by the user of the method. These mental steps contribute to the technical character of the method only if, in the context of the invention, they contribute to producing a technical effect serving a technical purpose.
For example, a method may specify steps which result in the selection of a product among a family of products based on various criteria, as well as a step of manufacturing the selected product. If said selection steps are carried out mentally, they contribute to the technical character of the method only to the extent that a technical effect can be derived from the features characterising the sub-family of selected products over the generic family of suitable products (T 619/02). If the selection steps rely on purely aesthetic criteria, they result in a non-technical selection and thus do not contribute to the technical character of the method. As another example, in a method of affixing a driver to a Coriolis mass flowmeter, steps specifying how to select the position of the driver so as to maximise the performance of the flowmeter make a technical contribution to the extent that they define that particular position (T 1063/05).
For additional information about methods of simulation, design and modelling, see G-II, 3.3.2. For methods of information modelling and the activity of programming a computer, see G-II, 3.6.2.

3.5.2 Schemes, rules and methods for playing games

Under Art. 52(2)(c) and (3), schemes, rules and methods for playing games are excluded from patentability, if claimed as such. The exclusion applies to rules for traditional games such as card or board games, as well as to game rules that underlie contemporary forms of gameplay such as in gambling machines or video games.
Art. 52(2)(c)
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Game rules define a conceptual framework of conventions and conditions that govern player conduct and how a game evolves in response to

decisions and actions by the players. They comprise the setup of the game, options that arise as gameplay unfolds, as well as goals defining progress in the game. They are normally perceived (or even agreed to) by the players as rules serving the explicit purpose of playing the game. Game rules are hence of an abstract, purely mental nature and are meaningful only in the gaming context (T 336/07). For example, a condition requiring two randomly drawn numbers to match for winning is a game rule.
Contemporary games, and in particular video games, are often characterised by complex interactive and narrative elements of a virtual game world. Such game elements govern how the game proceeds of its own accord (e.g. evolving characters and storylines) as well as how it proceeds in interaction with the player(s) (e.g. tapping along with the game soundtrack to make your character dance if rhythms match). Given that these elements are conceptual in nature, they qualify, in a wider sense, as rules for playing games according to Art. 52(2)(c) (T 12/08). This holds true irrespective of the fact that they might be untold or revealed only while playing.
If the claimed subject-matter specifies technical means for implementing game rules, it has a technical character. For example, when implementing the aforementioned condition of matching random numbers, the use of a computer calculating a pseudo-random sequence or of mechanical means such as cubic dice or uniformly sectored reels is sufficient to overcome an objection under Art. 52(2)(c) and (3).
Inventive step of a claim comprising a mix of game rules and technical features is examined in accordance with the problem-solution approach for mixed-type inventions as set out under G-VII, 5.4. As a principle, inventive step cannot be established by the game rules themselves, irrespective of how original they may be, or by their mere automation. It must rather be based on further technical effects of a technical implementation of the game, i.e. technical effects that go beyond those already inherent to the rules. For example, a networked implementation of a game of chance like bingo, in which numbers physically drawn by an operator undergo a random mapping prior to transmission to remote players, makes a technical contribution since the scrambling of results has the technical effect of securing a data transmission, analogous to encryption, while having no bearing on the actual playing of the game. In contrast, a reduction of memory, network, or computational resources achieved by limiting the complexity of a game does not overcome a technical constraint by a technical solution. Rather than solving the technical problem of improving the efficiency of an implementation, such a limitation would at best circumvent it (G-VII, 5.4.1). Similarly, the commercial success of a game product resulting from simplified rules is an incidental effect without a direct technical cause.
Inventive step of an implementation is to be assessed from the point of view of the skilled person, typically an engineer or a game programmer, who is tasked with implementing game rules as set by a game designer.

Mere claim drafting exercises such as paraphrasing non-technical game elements ("win computation means" for monitoring the number of game tokens) or abstracting them ("objects" instead of "game tokens") using terms that are technical only on the surface have no bearing on inventive step.

Game rules often are designed to entertain and keep the interest of players by way of psychological effects such as amusement, suspense, or surprise. Such effects do not qualify as technical effects. Similarly, giving rise to a balanced, fair or otherwise rewarding gameplay are psychological effects, not technical ones. Hence, rules and corresponding computations which determine a game score or a skill rating for players, even if computationally complex, are usually considered non-technical.

Highly interactive gameplay such as in video games involves technical means for sensing user input, updating the game state and outputting visual, audio or haptic information. Features defining such presentations of information and user interfaces are assessed according to G-II, 3.7 and 3.7.1. Cognitive content that informs the player about the current game state at a non-technical level, e.g. about a game score, the arrangement and suits of playing cards, the state and attributes of a game character is regarded as non-technical information. This equally holds for instructions presented on game boards or cards such as "go back to square one". An example of a technical context in which the manner of presenting information can make a technical contribution is the interactive control of real-time manoeuvres in a game world, the display of which is subject to conflicting technical requirements (T 928/03).

Aside from rules, the state of a game world may also evolve in accordance with numerical data and equations that model physical principles or pseudo-physical behaviour, especially in video games. The systematic calculation of updates to such game states amounts to a computerimplemented simulation based on these models (G 1/19). For the purpose of assessing inventive step in this context, the models are to be understood as defining a given constraint for a corresponding implementation on a computer (G-VII, 5.4). In contrast to effects that reside within the virtual game world or are otherwise inherent to the model already, a specific implementation of a simulation, if adapted to the internal functioning of a computer system, produces a technical effect. For instance, merely predicting the virtual trajectory of a billiard ball shot by the player, even if highly accurate, fails to solve a technical problem beyond its implementation. In contrast, adjusting the step sizes used in the distributed simulation of bullets fired in a multi-player online game based on current network latencies produces a technical effect.

Features which specify how to provide user input normally make a technical contribution (G-II, 3.7.1). However, a mapping of parameters obtained from known input mechanisms to parameters of a computer game qualifies as a game rule in a wider sense if it reflects the choice of the game designer, set

for the purpose of defining the game or making it more interesting or challenging (e.g. a condition specifying that a slide gesture on a touchscreen determines both the power and the spin of a virtual golf shot).
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3.5.3 Schemes, rules and methods for doing business

Subject-matter or activities which are of a financial, commercial, administrative or organisational nature fall within the scope of schemes, rules and methods for doing business, which are as such excluded from patentability under Art. 52(2)(c) and (3). In the rest of this section, any such subject-matter or activities will be subsumed under the term "business method".

Financial activities typically include banking, billing or accounting. Marketing, advertising, licensing, management of rights and contractual agreements, as well as activities involving legal considerations, are of a commercial or administrative nature. Personnel management, designing a workflow for a business process or communicating postings to a target user community based on location information are examples of organisational rules. Other activities typical of doing business concern operational research, planning, forecasting and optimisations in business environments, including logistics and scheduling of tasks. These activities involve collecting information, setting goals, and using mathematical and statistical methods to evaluate the information for the purpose of facilitating managerial decision-making.

If the claimed subject-matter specifies technical means, such as computers, computer networks or other programmable apparatus, for executing at least some steps of a business method, it is not limited to excluded subject-matter as such and thus not excluded from patentability under Art. 52(2)(c) and (3).

However, the mere possibility of using technical means is not sufficient to avoid exclusion, even if the description discloses a technical embodiment (T 388/04, T 306/04, T 619/02). Terms like "system" or "means" are to be looked at carefully, because a "system" might e.g. refer to a financial organisation and "means" to organisational units if it cannot be inferred from the context that these terms refer exclusively to technical entities (T 154/04).

Once it is established that the claimed subject-matter as a whole is not excluded from patentability under Art. 52(2) and (3), it is examined with respect to novelty and inventive step (G-I, 1). The examination of inventive step requires an assessment of which features contribute to the technical character of the invention (G-VII, 5.4).

Where the claim specifies a technical implementation of a business method, the features which contribute to the technical character of the claim are in most cases limited to those specifying the particular technical implementation.

Features which are the result of technical implementation choices and not part of the business method contribute to the technical character and thus

have to be duly taken into account. This is illustrated with the following example: The claim defines a computerised networked system which allows customers to obtain audio-visual content about selected products using computers installed at each sales outlet of a company, all connected
Art. 52(2)(c)
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to a central server with a central database storing the audio-visual content as electronic files. The distribution of the electronic files from the central server to the sales outlets could be technically implemented either by enabling download of individual files directly from the central database to the computer on request of a customer or, alternatively, by transferring a plurality of selected electronic files to each sales outlet, storing these files in a local database of the sales outlet and retrieving the corresponding file from the local database when audio-visual content is requested by a customer at the sales outlet. Choosing one implementation among these two options lies within the competence of a technically skilled person, such as a software engineer, as opposed to, for example, specifying that the set of audio-visual contents offered is different for each sales outlet, which would typically be within the competence of a business expert. Features of the claim specifying any of these two possible technical implementations contribute to the technical character of the invention, whereas features specifying the business method do not.

In the case of claims directed to a technical implementation of a business method, a modification to the underlying business method aimed at circumventing a technical problem, rather than addressing this problem in an inherently technical way, is not considered to make a technical contribution over the prior art. In the context of an automation of a business method, effects which are inherent in the business method do not qualify as technical effects (G-VII, 5.4.1).

For instance, an automated accounting method that avoids redundant bookkeeping may be considered to require fewer computer resources in terms of computer workload and storage requirements. These advantages, in so far as they result from a reduction of the number of operations to be performed and the amount of data to be considered due to the business specification of the accounting method, are inherent to the accounting method itself and hence do not qualify as technical effects.

Another example is based on an electronic auction that is performed by successively lowering the price until the price is fixed by the remote participant who first transmits a message. Since messages may be received out of order due to possible transmission delays, each message contains timestamp information. Changing the auction rules to obviate the need for timestamp information amounts to circumventing the technical problem of transmission delays rather than solving it with technical means (T 258/03). As a further example, in a method for carrying out electronic financial transactions with credit cards at a point of sale, the administrative decision to dispense with the need to obtain the name or address of the

buyer to authorise the transaction may result in saving time and reducing data traffic. However, this measure, on its own, is not a technical solution to the technical problem of the bandwidth bottleneck of communication lines and the limited capacity of server computers, but an administrative measure which does not contribute to the technical character of the claimed subject-matter.

The mere fact that the input to a business method is real-world data is not sufficient for the business method to contribute to the technical character of

the claimed subject-matter, even if the data relate to physical parameters (e.g. geographic distances between sales outlets) (T 154/04, T 1147/05, T 1029/06). See also G-II, 3.3.

In a computer-implemented method for facilitating managerial decision-making, automatically selecting from a set of business plans the most cost-effective one which also enables meeting certain technical constraints (e.g. to achieve a targeted reduction in environmental impact) is not considered to make a technical contribution beyond the computer-implementation.

The mere possibility of serving a technical purpose is not enough for a method to contribute to the technical character of the invention. For example, a claim to a "method of resource allocation in an industrial process" encompasses pure business processes and services in finance, administration, or management, without limiting the method to any specific technical process due to the breadth of meaning of the term "industry".

The result of a business method may be useful, practical or saleable but that does not qualify as a technical effect.

Business method features, e.g. administrative features, can be found in different contexts. For example, a medical support system may be configured to deliver information to the clinician on the basis of data obtained from patient sensors, and only if such data is not available, on the basis of data provided by the patient. The prioritisation of the sensor data over the data provided by the patient is an administrative rule. Establishing it lies within the competence of an administrator, e.g. the head of the clinic, rather than within that of an engineer. As an administrative rule with no technical effect, it does not contribute to the technical character of the claimed subject-matter and may be used in the formulation of the objective technical problem as a constraint that has to be met when assessing inventive step (G-VII, 5.4). For further examples of applying the problem-solution approach to assess inventive step for subject-matter comprising business-method features, see G-VII, 5.4.2.1-5.4.2.3.

3.6 Programs for computers

Computer programs are excluded from patentability under Art. 52(2)(c) and (3) if claimed as such. However, following the generally applicable criteria for Art. 52(2) and (3) (G-II, 2), the exclusion does not apply to computer programs having a **technical character**.

In order to have a technical character, and thus not be excluded from

patentability, a computer program must produce a "**further technical effect**" when run on a computer. A "further technical effect" is a technical effect going beyond the "normal" physical interactions between the program (software) and the computer (hardware) on which it is run. The normal physical effects of the execution of a program, e.g. the circulation of electrical currents in the computer, are not in themselves sufficient to confer technical character to a computer program (T 1173/97 and G 3/08).

Art. 52(2)(c)

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Examples of further technical effects which confer technical character to a computer program are the control of a technical process or of the internal functioning of the computer itself or its interfaces (see G-II, 3.6.1).

The presence of a further technical effect is assessed without reference to the prior art. It follows that the mere fact that a computer program serving a non-technical purpose requires less computing time than a prior-art program serving the same non-technical purpose does not on its own establish the presence of a further technical effect (T 1370/11). Likewise, comparing a computer program with how a human being would perform the same task is not a suitable basis for assessing if the computer program has a technical character (T 1358/09).

If a further technical effect of the computer program has already been established, the computational efficiency of an algorithm affecting the established technical effect contributes to the technical character of the invention and thus to inventive step (e.g. where the design of the algorithm is motivated by technical considerations of the internal functioning of the computer; see also G-II, 3.3).

A computer program cannot derive a technical character from the mere fact that it has been designed such that it can be automatically performed by a computer. "Further technical considerations", typically related to the technical considerations of the internal functioning of the computer, going beyond merely finding a computer algorithm to perform a task are needed. They have to be reflected in claimed features that cause a further technical effect (G 3/08).

If a claim is directed to a computer program which does not have a technical character, it is objected to under Art. 52(2)(c) and (3). If it passes the test for having technical character, the examiner then proceeds to the questions of novelty and inventive step (see G-VI and G-VII, in particular G-VII, 5.4).

Computer-implemented inventions

"Computer-implemented invention" is an expression intended to cover claims which involve computers, computer networks or other programmable apparatus wherein at least one feature is realised by means of a computer program. Claims directed to computer-implemented inventions may take the forms described in F-IV, 3.9 and subsections.

A computer program and a corresponding computer-implemented method are distinct from each other. The former refers to a sequence of

computer-executable instructions specifying a method while the latter refers to a method being actually performed on a computer.
Claims directed to a computer-implemented method, a computer-readable storage medium or a device cannot be objected to under Art. 52(2) and (3) as any method involving the use of technical means (e.g. a computer) and any technical means itself (e.g. a computer or a computer-readable storage March 2022 Guidelines for Examination in the EPO Part G – Chapter II-17 medium) have technical character and thus represent inventions within the meaning of Art. 52(1) (T 258/03, T 424/03, G 3/08).

3.6.1 Examples of further technical effects

If a method has a technical character over and above the mere fact that it is computer-implemented, a corresponding computer program specifying that method produces a further technical effect when run on a computer. For example, a computer program which specifies a method of controlling an anti-lock braking system in a car, determining emissions by an X-ray device, compressing video, restoring a distorted digital image, or encrypting electronic communications brings about a further technical effect when it is run on a computer (see G-II, 3.3).
Furthermore, if a computer program is designed based on specific technical considerations of the internal functioning of the computer on which it is to be executed, such as by being adapted to the specific architecture of the computer, it may be considered to produce a further technical effect. For example, computer programs implementing security measures for protecting boot integrity or countermeasures against power analysis attacks have a technical character since they rely on a technical understanding of the internal functioning of the computer.
Similarly, computer programs controlling the internal functioning or operation of a computer, such as processor load balancing or memory allocation, normally produce a further technical effect (see, however, G-VII, 5.4.2.3 for an example of a case where the controlling is based on a non-technical scheme).
Programs for processing code at low level, such as builders or compilers, may well have a technical character. For example, when building runtime objects from development objects, regenerating only those runtime objects resulting from modified development objects contributes to producing the further technical effect of limiting the resources needed for a particular build.

3.6.2 Information modelling, activity of programming and programming languages

Information modelling is an intellectual activity devoid of technical character and typically carried out by a systems analyst in a first stage of software development, to provide a formal description of a real-world system or process. Consequently, specifications of a modelling language, the structure of an information modelling process (e.g. use of a template) or the maintenance of models likewise have no technical character (T 354/07). Similarly, properties inherent to information models, like re-usability,

platform-independence or convenience for documentation, are not regarded as technical effects (T 1171/06).
If an information model is purposively used in the context of an invention to solve a specific technical problem by providing a technical effect, it can contribute to the technical character of the invention (see also G-II, 3.3.2 and 3.5.1).
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Features specifying how the model is actually stored (e.g. using relational database technology) can also make a technical contribution.
Conceptual methods describing the process of software development (meta-methods) normally have no technical character. For example, in a computer-implemented method for generating program code for a control task, a feature specifying that a platform-independent model is converted to a platform-dependent model, from which program code adapted to the target platform is derived, makes no technical contribution in so far as the performance of the control task itself is not affected.
The **activity of programming**, in the sense of writing code, is an intellectual, non-technical activity, to the extent that it is not used in the context of a concrete application or environment to contribute in a causal manner to the production of a technical effect (G 3/08, T 1539/09).
For example, reading a data type parameter from a file as input to a computer program, rather than defining the data type in the program itself, is merely a programming option when writing code, which has *per se* no technical character. The same applies to naming conventions for object names for facilitating the intelligibility and the management of program code.
Defining and providing a **programming language** or a programming paradigm such as object-oriented programming does not *per se* solve a technical problem, even if its particular syntax and semantics enable the programmer to develop a program with greater ease. Easing the intellectual effort of the programmer is *per se* not a technical effect.
When assessing an invention relating to a **programming environment**, the features pertaining to the programming language do not normally contribute to its technical character. For example, in a visual programming environment, the provision of specific graphical building blocks is part of the programming language and makes no technical contribution if the only effect is easing the intellectual effort of the programmer. The provision of particular programming constructs may enable a programmer to write shorter programs, but that does not qualify as a technical effect since any resulting reduction of program length ultimately depends on how the programming constructs are used by a human programmer. In contrast, automatically processing machine code by dividing it into an instruction chain and an operand chain and replacing repeating instruction sets by macro-instructions so as to generate optimised code of reduced memory size makes a technical contribution. In this case, the effect does not depend on how a human programmer makes use of the macro-instructions.

Features of a programming environment that relate to its graphical user interface, e.g. visualisations and data input mechanisms, are to be assessed as indicated in G-II, 3.7 and 3.7.1.
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3.6.3 Data retrieval, formats and structures
A computer-implemented data structure or data format embodied on a medium or as an electromagnetic carrier wave has technical character as a whole and thus is an invention within the meaning of Art. 52(1).
A data structure or format contributes to the technical character of the invention if it has an intended technical use and it causes a technical effect when used according to this intended technical use. Such a potential technical effect related to an implied technical use is to be taken into account in assessing inventive step (G 1/19). This may happen if the data structure or format is functional data, i.e. if it has a technical function in a technical system, such as controlling the operation of the device processing the data. Functional data inherently comprise, or map to, the corresponding technical features of the device (T 1194/97). Cognitive data, on the other hand, are those data whose content and meaning are only relevant to human users and do not contribute to producing a technical effect (see however, G-II, 3.7 for presentation of information to a user in a continued and/or guided human-machine interaction process).
For example, a record carrier for use in a picture retrieval system stores coded pictures together with a data structure defined in terms of line numbers and addresses which instruct the system how to decode and access the picture from the record carrier. This data structure is defined in terms which inherently comprise the technical features of the picture retrieval system, namely the record carrier and a reading device for retrieving pictures therefrom in which the record carrier is operative. It thus contributes to the technical character of the record carrier, whereas the cognitive content of the stored pictures (e.g. photograph of a person or landscape) does not.
Similarly, an index structure used for searching a record in a database produces a technical effect since it controls the way the computer performs the search operation (T 1351/04).
Another example is an electronic message with a header and a content section. Information in the header comprises instructions which are automatically recognised and processed by the receiving message system. This processing in turn determines how the content elements are to be assembled and presented to its final recipient. The provision of such instructions in the header contributes to the technical character of the electronic message, whereas the information in the content section, representing cognitive data, does not (T 858/02).
A data structure or a data format may have features which may not be characterised as cognitive data (i.e. not for conveying information to a user) but which nevertheless do not make a technical contribution. For example, the structure of a computer program may merely aim at facilitating the task

of the programmer, which is not a technical effect serving a technical purpose. Furthermore, data models and other information models at an abstract logical level have *per se* no technical character (see G-II, 3.6.2).
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Digital data is used to control devices in additive manufacturing (AM), which is the general term for technologies manufacturing physical objects by successive addition of material based on a digital representation of the geometry of the object. If the data defines the instructions for operating the AM device, it makes a technical contribution as illustrated in the following example:
Example
A computer-readable medium storing data which defines both a digital representation of the product of claim 1 and operating instructions adapted to control an AM device to fabricate the product using the digital representation of the product when said data is relayed to the AM device.
Remarks
A computer-readable medium is a technical object, so no objection under Art. 52(2) and (3) arises.
Since the data comprises both a digital description of the (physical) product of claim 1 and associated operating instructions adapted to control an AM device, it is *intended* to be used to control an AM device to fabricate the product. This technical use of the data is implied across substantially the whole scope of the claim. Construing the present claim to encompass a non-technical use of merely visualising the data would be artificial. The technical effect of fabricating the physical product defined in claim 1 that is achieved when the data is used according to its intended use is thus a potential technical effect that is to be taken into account when assessing inventive step. The digital representation of the product makes a technical contribution to the extent that it defines technical features of the fabricated physical product.
However, if such a technical use of the data were not implied by the claim, the potential technical effect of the data of fabricating the physical product could not be taken into account when assessing inventive step as it would not be implied across substantially the whole scope of the claim. This would be the case, for instance, if the data defined only a digital description or 3D model of the product that is not adapted to additive manufacturing of the product and could be used to merely visualise the product in a CAD software tool. Abstract descriptions or models are not considered technical even if the described entities are technical (see G-II, 3.3.2). In such a case, the stored non-technical data would not make a technical contribution.

3.6.4 Database management systems and information retrieval

Database management systems are technical systems implemented on computers to perform the technical tasks of storing and retrieving data using various data structures for efficient management of data. A method performed in a database management system is thus a method which uses technical means and is therefore not excluded from patentability under

Art. 52(2) and Art. 52(3).
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Features specifying the internal functioning of a database management system are normally based on technical considerations. Therefore, they contribute to the technical character of the invention and are taken into account for the assessment of inventive step. For instance, technical considerations are involved in improving system throughput and query response times by automatically managing data using various data stores with different technical properties such as different levels of consistency or performance (T 1924/17, T 697/17).
Database management systems execute structured queries, which formally and precisely describe the data to be retrieved. Optimising the execution of such structured queries with respect to the computer resources needed (such as CPU, main memory or hard disk) contributes to the technical character of the invention since it involves technical considerations concerning the efficient exploitation of the computer system.
However, not all features implemented in a database management system necessarily make a technical contribution by virtue of this fact alone. For example, a feature of a database management system for accounting costs related to the use of the system by different users may be regarded as not making a technical contribution.
Data structures, such as an index, hash table or a query tree, used in database management systems to facilitate access to data or for the execution of structured queries contribute to the technical character of the invention. Such data structures are functional since they purposively control the operation of the database management system to perform said technical tasks. Conversely, data structures defined solely by the cognitive information they store are not considered to contribute to the technical character of the invention beyond the mere storage of data (see also G-II, 3.6.3).
A distinction is made between executing structured queries by a database management system and information retrieval. The latter includes searching for information in a document, searching for documents themselves, and also searching for metadata that describe data such as texts, images or sounds. The query may be formulated by the user in need of information, typically informally using natural language without a precise format: the user may enter search terms as a query in web search engines to find relevant documents or submit an exemplary document to find similar documents. If the method of estimating relevance or similarity relies solely on non-technical considerations, such as the cognitive content of the items to be retrieved, purely linguistic rules or other subjective criteria (e.g. items found relevant by friends in social networks), it does not make a technical contribution.
The translation of linguistic considerations into a mathematical model with the aim of enabling the linguistic analysis to be done automatically by a computer can be seen as involving, at least implicitly, technical

considerations. However, this is not enough to guarantee the technical character of the mathematical model. Further technical considerations such Part G – Chapter II-22 Guidelines for Examination in the EPO March 2022 as those relating to the internal functioning of the computer system are needed.
For example, a mathematical model for calculating the probability that a given term is similar in meaning to another term by analysing the co-occurrence frequency of the two terms in a collection of documents does not make a technical contribution *per se* since it is based on considerations of a purely linguistic nature (i.e. based on the assumption that terms which are related are more likely than unrelated terms to occur in the same documents). The search results produced using this method of similarity calculation would differ from prior art that adopts another mathematical model only in that information with different cognitive content would be retrieved. This is a non-technical distinction and does not qualify as a technical effect. In this context of retrieval based on similarity of meaning of terms, the concept of "better search" is subjective (T 598/14). In contrast, optimising the execution time of structured queries in a database management system as discussed above is a technical effect.
See also G-II, 3.3.1, for artificial intelligence and machine learning algorithms.

3.7 Presentations of information

Presentations of information within the meaning of Art. 52(2)(d) are understood as the conveying of information to a user. It concerns both the cognitive content of the information presented and the manner of its presentation (T 1143/06, T 1741/08). It is not limited to visual information, but also covers other presentation modalities, e.g. audio or haptic information. However, it does not extend to the technical means used for generating such presentations of information.
Furthermore, conveying information to a user is to be distinguished from technical representations of information directed to a technical system which will process, store or transmit that information. Features of data encoding schemes, data structures and electronic communication protocols which represent functional data as opposed to cognitive data are not regarded as presentations of information within the meaning of Art. 52(2)(d) (T 1194/97).
When assessing exclusion from patentability under Art. 52(2) and (3), the claimed subject-matter has to be considered as a whole (G-II, 2). In particular, a claim directed to or specifying the use of any technical means for presenting information (e.g. a computer display) has, as a whole, technical character and is thus not excluded from patentability. As another example, a claim directed to a kit comprising a product (e.g. a bleaching composition) and further features such as instructions for use of the product or reference information for evaluating the results obtained, wherein said further features have no technical effect on the product, is not excluded since the claim has a technical feature: a product comprising a composition

of matter.
Once it is established that the claimed subject-matter as a whole is not excluded from patentability under Art. 52(2) and (3), it is examined in
Art. 52(2)(d)
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respect of the other requirements of patentability, in particular novelty and inventive step (G-I, 1).
During the assessment of inventive step, features related to the presentation of information are analysed to determine if, in the context of the invention, they contribute to producing a technical effect serving a technical purpose. If not, they make no technical contribution and cannot support the presence of an inventive step (G-VII, 5.4). To determine whether a technical effect is produced, the examiner assesses the context of the invention, the task the user carries out and the actual purpose served by the particular presentation of information.
A feature defining a presentation of information produces a technical effect if it credibly assists the user in performing a technical task by means of a continued and/or guided human-machine interaction process (T 336/14 and T 1802/13). Such a technical effect is considered credibly achieved if the assistance to the user in performing the technical task is objectively, reliably and causally linked to the feature. This would not be the case if the alleged effect depends on subjective interests or preferences of the user. For example, for some users it is easier to understand data when it is displayed as numerical values, whereas others might prefer a colour-coded display. The choice of the one or other manner of displaying the data is thus not considered to have a technical effect (T 1567/05). Similarly, whether or not it is easier to understand audio information conveyed as a musical scale instead of spoken words is a matter concerned only with the cognitive abilities of the user. As another example, allowing the user to set parameters determining the information to be presented or to select the manner of its presentation does not make a technical contribution if it merely accommodates subjective user preferences.
Determining the extent to which a particular presentation of information may be considered to credibly support the user in performing a technical task may be difficult. It may be simplified during the assessment of inventive step by comparing the invention with the prior art, thus allowing the analysis to be limited to the distinguishing features (G-VII, 5.4, paragraph 5). This comparison may reveal that the potential support for the performance of the technical task is already achieved in the prior art, with the consequence that the distinguishing features make no technical contribution (e.g. relate only to non-technical subjective user preferences).
A feature relating to the presentation of information may commonly be considered to specify:
(i) the cognitive content of the information presented, i.e. defining "what" is presented; or
(ii) the manner in which the information is presented, i.e. defining "how"

the information is presented.
This categorisation is adopted to allow for a more detailed discussion of technical effects in the rest of this section. It is noted that these categories are not meant to be exhaustive. Also, there are cases in which a feature
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falls into both categories. For example, a step of "displaying the surname of a customer in capital letters" in a claimed method defines both the cognitive content of the presented information (surname of a customer) and the manner of its presentation (in capital letters). Such a feature may be considered to consist in fact of two features: the displayed text is the surname of a customer (falling into the first category) and the displayed text is shown in capital letters (falling into the second category). The manner of presentation itself might additionally convey cognitive information. For example, the capitalised part of a name may, as a matter of convention, indicate which part is the surname.
(1) What (which information) is presented?
If the cognitive content of the information presented to the user relates to an internal state prevailing in a technical system and enables the user to properly operate this technical system, it has a technical effect. An internal state prevailing in a technical system is an operating mode, a technical condition or an event which is related to the internal functioning of the system, may dynamically change and is automatically detected. Its presentation typically prompts the user to interact with the system, for example to avoid technical malfunctions (T 528/07).
Static or predetermined information about technical properties or potential states of a machine, specifications of a device or operating instructions do not qualify as an internal state prevailing in the device. If the presentation of static or predetermined information merely has the effect of helping the user with the non-technical tasks preceding the technical task, it does not make a technical contribution. For example, the effect that the user is not required to know or memorise a sequence of buttons to be operated prior to configuring a device is not a technical effect.
Non-technical information such as the state of a casino game, a business process or an abstract simulation model is exclusively aimed at the user for subjective evaluation or non-technical decision-making. It is not directly linked to a technical task. Therefore, such information does not qualify as an internal state prevailing in a technical system.
(2) How is the information presented?
A feature in this category typically specifies the form or arrangement in which, or the timing at which, information is conveyed to the user (e.g. on a screen). One example is a diagram designed solely for conveying information. Specific technical features related to, for example, the way audio signals or images are generated are not regarded as a manner in which information is presented.
Features defining a visualisation of information in a particular diagram or layout are normally not considered to make a technical contribution, even if

the diagram or layout arguably conveys information in a way which a viewer may intuitively regard as particularly appealing, lucid or logical.
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For instance, dealing with limited available screen space is part of designing presentations of information for human viewing and therefore not an indication of technicality *per se*. The general idea of giving an overview of a plurality of images in a limited display area by displaying a single image and sequentially replacing it with other images is not based on technical considerations, but is a matter of layout design. Similarly, arranging objects within available screen space by eliminating "white space" between window panes follows the same layout principles as would apply to the layout of a magazine cover and does not involve technical considerations.
On the other hand, if the manner of presentation credibly assists the user in performing a technical task by means of a continued and/or guided human-machine interaction process, it produces a technical effect (T 1143/06, T 1741/08, T 1802/13). For example, displaying several images side by side in low resolution and allowing selection and display of an image at higher resolution conveys information to the user in the form of a technical tool that enables the user to perform the technical task of interactively searching and retrieving stored images more efficiently. Storing digital images at different resolutions gives rise to the technical effect of allowing the simultaneous overview display of several images (T 643/00). As another example, in a video soccer game, the particular manner of conveying to the user the location of the nearest teammate by dynamically displaying a guide mark on the edge of the screen when the teammate is off-screen produces the technical effect of facilitating a continued human-machine interaction by resolving conflicting technical requirements: displaying an enlarged portion of an image and maintaining an overview of a zone of interest which is larger than the display area (T 928/03). As a further example, in the context of a visual aid for a surgeon, if, in the course of surgery, the current orientation of a medical ball joint implant is displayed in a manner which credibly assists the surgeon to correct the position of the implant in a more precise manner, this is considered to provide a technical effect.
Effects relying on human physiology
When a manner of presenting information produces in the mind of the user an effect which does not depend on psychological or other subjective factors but on physical parameters which are based on human physiology and can be precisely defined, that effect may qualify as a technical effect. The manner of presenting information then makes a technical contribution to the extent that it contributes to this technical effect. For example, displaying a notification on one of a plurality of computer screens near the user's current visual focus of attention has the technical effect that it is more or less guaranteed to be seen immediately (compared e.g. with an arbitrary placement on one of the screens). In contrast, the decision to

show only urgent notifications (compared e.g. to all notifications) is based only on psychological factors and thus makes no technical contribution. Minimising information overload and distraction is not considered to qualify *per se* as a technical effect (T 862/10). As another example, displaying a stream of images in which the parameters for delay and change in the content between successive images are computed on the basis of physical

properties of human visual perception in order to achieve a smooth transition is considered to make a technical contribution (T 509/07).
If information (e.g. a visual or audio stimulus) is presented to a person for the purpose of producing in that person a physiological reaction (e.g. involuntary eye gaze) which can be measured in the context of assessing a medical condition (e.g. eyesight, hearing impairment or brain damage), that presentation of information may be considered to produce a technical effect.

Effects relying on mental activities of the user

Where the claimed subject-matter comprises a feature of presenting information to a user, be it of category (i) or (ii), an evaluation by the user is involved. Although such an evaluation *per se* is a mental act (Art. 52(2)(c)), the mere fact that mental activities are involved does not necessarily qualify subject-matter as non-technical. For example, in T 643/00 discussed above, the user makes an evaluation based on an overview of low-resolution images in order to locate and objectively recognise a desired image. This mental evaluation may be considered to be an intermediate step steering the image search and retrieval process and thus forms an integral part of a solution to a technical problem. Such a solution relies neither on facilitating the human tasks of understanding, learning, reading or memorising nor on influencing the user's decision as to which image is to be searched. It provides a mechanism for inputting a selection which would not be possible if the images were not displayed in that specific arrangement.

On the other hand, if the choice or layout of information presented aims exclusively at the human mind, in particular to help the user to take a non-technical decision (e.g. which product to buy based on a diagram showing properties of products), no technical contribution is made.

3.7.1 User interfaces

User interfaces, in particular graphical user interfaces (GUIs), comprise features of presenting information and receiving input in response as part of human-computer interaction. Features defining user input are more likely to have a technical character than those solely concerning data output and display, because input requires compatibility with the predetermined protocol of a machine, whereas output may be largely dictated by the subjective preferences of a user. Features concerning the graphic design of a menu (such as its look and feel) which are determined by aesthetic considerations, subjective user preferences or administrative rules do not contribute to the technical character of a menu-based user interface.

Evaluation of features related to output of data is addressed in G-II, 3.6.3. The present section focuses on evaluating features relating to how a user can provide input.

Features which specify a mechanism enabling user input, such as entering text, making a selection or submitting a command, are normally considered to make a technical contribution. For example, providing in a GUI an alternative graphical shortcut allowing the user to directly set different

processing conditions, such as initiating a printing process and setting the number of copies to be printed by dragging and reciprocated movement of a document icon onto a printer icon, makes a technical contribution. On the other hand, supporting user input by providing information facilitating only the user's mental decision-making process during this task (e.g. helping the user in deciding what to input) is not considered as making a technical contribution (T 1741/08).

Assisting a user in entering text in a computer system by providing a predictive input mechanism is a technical function. However, generating word variants to be displayed for the predictive input mechanism is, in itself, a non-technical problem. The linguistic model used to solve this non-technical problem does not, on its own, make a technical contribution. If technical considerations are involved to implement the linguistic model on a computer, such as those relating to the internal functioning of a computer, then a technical effect may arise.

Where the actual achievement of effects like simplifying the user's actions or providing more user-convenient input functions depends exclusively on subjective user abilities or preferences, such effects may not form the basis of an objective technical problem to be solved. For example, a reduction of the number of interactions required to perform the same input is not credibly achieved if it materialises only for some usage patterns that occur depending on the user's level of expertise or subjective preferences.

Manners of providing input, such as gestures or keystrokes, that merely reflect subjective user preferences, conventions or game rules and from which a physical ergonomic advantage cannot be objectively established, do not make a technical contribution. However, performance-oriented improvements to the detection of input, such as allowing faster or more accurate gesture recognition or reducing the processing load of the device when performing recognition, do make a technical contribution.

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). Antipersonnel mines are an obvious example.

Examples in the area of biotechnological inventions as laid down in Rule 28 are listed in G-II, 5.3. G 1/03 explains that practical examples under

Art. 53(a) arise from the fact that not everything can be done to human beings that can be done to other living beings. For example, the avoidance of offspring that are unwanted because of certain properties (sex, colour, health) and for economic reasons may be quite legitimate for domestic animals but when applied to human beings it would be contrary to "*ordre public*" or morality.

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

Art. 53(a)

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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, an objection is 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.

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 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.

4.1.2 Offensive and non-offensive use

Special attention must 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, where use by a burglar is offensive and use by a locksmith in an 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 also allows 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 is 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.

Art. 53(a)

4.2 Surgery, therapy and diagnostic methods

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 is 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. 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).

The exception under Art. 53(c) does not extend to **new** products, particularly substances or compositions, for use in these methods of treatment or diagnosis.

Where a substance or composition is already known, (notional) novelty can be derived from a new medical use in accordance with Art. 54(4) and (5). Pursuant to Art. 54(4), a known substance or composition may still be patented for use in a method referred to in Art. 53(c) if the known substance or composition has not previously been disclosed for use for any such method ("**first medical use**"). A claim to a known substance or composition for the first use in surgical, therapeutic and/or diagnostic methods must 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/in vivo diagnostics/surgery" (see G-VI, 7.1).

Furthermore, if the known substance or composition was previously disclosed for use in surgery, therapy or diagnostic methods practised on the human or animal body, a patent may still be obtained according to Art. 54(5) for any second or further use of the substance in these methods

provided that said use is novel and inventive ("**further medical use**"). A claim to a further medical use of a known substance must be in the form: "Substance or composition X" followed by the indication of the **specific** therapeutical/in vivo 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)

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 living 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 such methods are

Art. 53(c)
Art. 54(4)
Art. 54(5)
Art. 53(c)

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of a technical and not essentially biological character (see G-II, 5.4.2). 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 as long 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 must 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 must 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).

Claims to medical devices, computer programs and storage media which comprise subject-matter corresponding to that of a method for treatment of the human or animal body by surgery or therapy or to that of a diagnostic method practised on the human or animal body are not to be objected to under Art. 53(c), because only method claims may fall under the exception of Art. 53(c).

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 falling under the exception of Art. 53(c) should be assessed on a case-by-case basis, taking the individual merits of each case into account. The reason for the exception is to allow medical and veterinary practitioners 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 generally carried out in a non-medical, commercial environment are not excluded from patentability. They include 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. An example is a method for retraction of the sulcus of a tooth using a paste and a cap to prepare an impression of the tooth to manufacture a dental crown: the possible damage is limited to the superficial epithelium, the only risks are the superficial bleeding and inflammation which rapidly heal and the specific training needed to perform the method is minimal.
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).
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The exclusion under Art. 53(c) applies to multi-step methods which comprise or encompass at least one 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 (G 1/07, Reasons 4.2.2). For the general principles governing disclaimers, see H-V, 4. The overall patentability of the amended claim will however depend on its compliance with the other requirements of the EPC, which are assessed on a case-by-case basis.
If a surgical method claim is open to objection under Art. 53(c), this also applies to a corresponding claim directed to a computer-assisted surgical method. In other words, surgical methods for which European patents cannot be granted according to Art. 53(c) do not avoid exclusion merely through computer assistance.
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). It is concerned with bringing the body from a pathological state back into its normal, healthy state or preventing a pathological state. Where a method is directed to the treatment of a human or animal body that is in a normal, healthy state and, even if subject to some discomfort, not likely to develop a pathological state due to the discomfort, providing relief from the discomfort is not necessarily a therapy. For example, cooling an animal subject to hot weather conditions does not cure or lessen the symptoms of any disorder or malfunction of the

animal's body, nor does it reduce the possibility of contracting any disorder or malfunction, since no such disorder or malfunction would normally occur if the animal were not cooled (T 385/09).
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) is 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).
The exclusion under Art. 53(c) applies to multi-step methods which comprise or encompass at least one therapeutic step. 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 step of treatment by therapy from the wording of the claim (G 1/07). For the general principles governing disclaimers, see H-V, 4. The overall patentability of the amended

claim will however depend on its compliance with the other requirements of the EPC, which are assessed on a case-by-case basis.
If a method claim directed to therapy is open to objection under Art. 53(c), this also applies to a corresponding claim directed to a computer-implemented therapeutic method (T 1680/08). In this respect, the same observations as in G-II, 4.2.1.1, for computer-implemented surgical methods apply.

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) and thus excluded from patentability, 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 6 in the Annex to F-IV). Due account must 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).

Additionally, a method is only regarded as a diagnostic method within the meaning of Art. 53(c), and thus excluded from patentability, if all method steps of a technical nature belonging to the preceding steps which are constitutive for making the diagnosis, i.e. phases (i)-(iii), satisfy the criterion "practised on the human or animal body". However, the steps of phases (ii) and (iii) which consist in comparing the data collected in the examination phase with standard values and in finding a significant deviation resulting from the comparison are not subject to this criterion, because these activities are predominantly of a non-technical nature and are normally not practised on the human or animal body. Therefore, in most cases only

phase (i), which relates to the examination phase and involves the collection of data, can actually be of a technical nature within the meaning of G 1/04 and therefore concerned with the criterion "practised on the human or animal body" (see T 1197/02, T 143/04, T 1016/10).

It is noted that only the steps strictly describing phases (i)-(iv) have to be taken into account in determining the diagnostic character of the claimed method. Additional, preparatory or intermediate steps which may be introduced into the claimed method are irrelevant for this question (see T 1197/02, T 143/04, T 1016/10). For example, preparatory steps which concern the adjustment or preparation of the apparatus with which the collection of data will be performed may be comprised in a method claim. However, these additional features are not part of any of phases (i)-(iii), which are constitutive for making the diagnosis. Likewise, data processing using an automated apparatus is not actually part of the examination phase which involves the collection of data, but it results from a subsequent step, intermediate between data collection and the comparison of the collected data with standard values. The issue of whether or not such additional steps are of a technical nature and practised on the human or animal body is, therefore, irrelevant for the assessment of whether a claimed method is a diagnostic method falling under the exception clause of Art. 53(c).

In order to determine whether a method step of a technical nature fulfils the criterion "practised on the human or animal body" 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 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

Although in general a medical claim directed to tests carried out on "animals" must exclude from its scope the use of human beings as "test animals" (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. It is assumed that, unless there is evidence to the contrary, such trials are performed under strictly controlled conditions and with the informed

consent of the patient concerned. In such cases, no objection under Art. 53(a) is raised (see however G-II, 4.2.1.2).

5. Exclusions and exceptions for biotechnological inventions

5.1 General remarks and definitions

"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

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. Judgments of the Court of Justice of the European Union on the interpretation of EU Directive 98/44/EC are not binding on the EPO. Still, they may be considered as being persuasive (T 2221/10 and T 1441/13).
Biotechnological inventions are also patentable if they concern an item on the following non-exhaustive list:
(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).

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 26(2) and (3)
Rule 27
Rule 26(1)
Rule 27(a)
Rule 29(1) and (2)
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The examination of a patent application or a patent for gene sequences or partial sequences is 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);
(ii) Plants or animals if the technical feasibility of the invention is not confined to a particular plant or animal variety and if said plants or animals are not exclusively obtained by means of an essentially biological process
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). However, said plants or animals must not be exclusively obtained by means of an essentially biological process (see G-II, 5.4).
The exclusion regarding plants and animals exclusively obtained by means of an essentially biological process applies to patent applications with a filing date and/or a priority date after 1 July 2017. It does not apply to patents granted before that date or to pending patent applications with a filing date and/or a priority date before 1 July 2017 (see G 3/19, OJ EPO 2020, A119).
If a technical feature of a claimed plant or animal, e.g. a single nucleotide exchange in the genome, can be the result of both a technical intervention (e.g. directed mutagenesis) and an essentially biological process (a natural allele), a disclaimer is necessary to delimit the claimed subject-matter to the technically produced product (see examples in G-II, 5.4.2.1 and G-II, 5.4). Such a disclaimer will

only be necessary for patent applications with a filing date and/or a priority date after 1 July 2017. A disclaimer will not be required for patents granted before that date or for pending patent applications with a filing date and/or a priority date before 1 July 2017 (see G 3/19, OJ EPO 2020, A119). If, on the other hand, the feature in question can be obtained by technical intervention only, e.g. a transgene, no disclaimer is necessary. For the general principles governing disclaimers, see H-V, 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) and therefore is not excluded from patentability. More detailed instructions on the exclusions on plant varieties can be found in G-II, 5.4.1.

(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 29(3)
Rule 27(b)
Rule 28(2)
Rule 27(c)

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"Microbiological process" means any process involving or performed upon or resulting in microbiological material.

5.3 List of exceptions (Rule 28)

In the area of biotechnological inventions, the following list of exceptions to patentability under Art. 53(a) and Art. 53(b) is laid down in Rule 28. Under Art. 53(a) 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. A possible immoral use is only to be taken into account if it is specifically considered or at least suggested in the application and can thus be found to constitute an avowed use (G-II, 4.1 and T 866/01).

According to Rule 28(2), plants and animals exclusively obtained by means of an essentially biological process are excluded from patentability. This exclusion regarding plants and animals exclusively obtained by means of an essentially biological process applies to patent applications with a filing date and/or a priority date after 1 July 2017. It does not apply to patents granted before that date or to pending patent applications with a filing date and/or a priority date before 1 July 2017 (see G 3/19, OJ EPO 2020, A119).

Under Art. 53(a), in conjunction with Rule 28(1), European patents are not to be granted in respect of biotechnological inventions which concern:

(i) Processes for cloning human beings

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
(iii) Uses of human embryos for industrial or commercial purposes
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(1)(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 (T 2221/10).
When examining subject-matter relating to human embryonic stem cells under Art. 53(a) and Rule 28(1)(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
Rule 26(6)
Rule 28(1)
Rule 28(1)(a)
Rule 28(1)(b)
Rule 28(1)(c)

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.
An application pertaining to human pluripotent stem cells, including human embryonic stem cells, uses thereof or products derived therefrom cannot be regarded as excluded from patentability under Art. 53(a) and Rule 28(1)(c) (T 0385/14) if (i) the application has an effective date (i.e. a valid priority date or, if no priority is claimed or the priority is not valid, a filing date) on or after 5 June 2003, and (ii) its technical teaching can be put into practice using human embryonic stem cells derived from parthenogenetically activated human oocytes.
Foetal and post-natal human cells are in principle not excluded from patentability.
Culture media, supports and apparatuses "suitable for" use with human embryonic cells, or even "specifically designed" for this purpose, are not *per se* excluded from patentability. Their production normally does not require the use of human embryos as base material.
The exclusion of the use 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).

(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

A claim directed to genetically modified animals or to processes for genetically modifying animals needs to meet the requirements of Rule 28(1)(d) and Art. 53(a) (see T 315/03 and T 19/90).

To fulfil the requirements of Rule 28(1)(d), the following needs to be established:

(a) that the subject-matter in question concerns a process for modifying the genetic identity of animals or animals resulting from that process,

(b) the likelihood of animal suffering,

(c) the likelihood of substantial medical benefit and

(d) the necessary correspondence between suffering and substantial medical benefit in terms of the animals claimed.

Rule 28(1)(d)

The level or standard of proof for establishing animal suffering and substantial medical benefit is likelihood. The correspondence has to be established according to the balance-of-probabilities approach (E-IV, 4.3).

For Article 53(a), a careful weighing-up of the suffering of animals and possible risks to the environment, on the one hand, and the invention's usefulness to mankind, on the other hand, are used to the extent that those two aspects are supported by evidence (see T 19/90 and T 315/03).

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).

The above must be applied to the whole scope of the claim.

For applications relating to non-genetically modified animals, in all cases where animal suffering or possible risks to the environment is involved, the provisions of Article 53(a) have to be assessed by considering the invention's usefulness to mankind (T 1553/15).

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).

A parthenote is neither a human body at a stage of its formation and development nor one of its elements (i.e. human germ cell); thus a parthenote or cells derived therefrom are in principle not excluded from patentability under Rule 29(1).

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 or essentially biological processes for the production of plants or animals

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".

Rule 28(2) excludes products (plants/animals and plant/animal parts) exclusively obtained by non-technical, i.e. essentially biological, processes. This exclusion regarding plants and animals exclusively obtained by means of an essentially biological process applies to patent applications with a filing date and/or a priority date after 1 July 2017. It does not apply to patents granted before that date or to pending patent applications with a filing date and/or a priority date before 1 July 2017 (see G 3/19, OJ EPO 2020, A119).

Rule 29(1)
Art. 53(b)
Rule 28(2)

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The exclusion extends to plants and animals exclusively obtained by means of an essentially biological process where no direct technical intervention in the genome of the plants or animals takes place, as the relevant parental plants or animals are merely crossed and the desired offspring is selected for. This is the case even if technical means are provided serving to enable or assist the performance of the essentially biological steps. In contrast, plants or animals produced by a technical process which modifies the genetic characteristics of the plant or animal are patentable.

The term **exclusively** is used here to mean that a plant or animal originating from a technical process or characterised by a technical intervention in the genome is not covered by the exclusion from patentability even if in addition a non-technical method (crossing and selection) is applied in its production.

Determining whether a plant or animal is obtained by exclusively biological means entails examining whether there is a change in a heritable characteristic of the claimed organism which is the result of a technical process exceeding mere crossing and selection, i.e. not merely serving to enable or assist the performance of the essentially biological process steps. Thus transgenic plants and technically induced mutants are patentable, while the products of conventional breeding are not.

Both targeted mutation, e.g. with CRISPR/Cas, and random mutagenesis such as UV-induced mutation are such technical processes. When looking at the offspring of transgenic organisms or mutants, if the mutation or transgene is present in said offspring it is not produced exclusively by an essentially biological method and is thus patentable.

Furthermore, for living matter to be patentable, it must be possible to reproduce it in a way that has exactly the same technical features. Reproducibility can be assured for example:
(1) By a deposit of the living matter (seeds, microbiological strains). The deposited material must be publicly available and such that the invention can actually be reproduced starting from it. If, for example, a novel and inventive trait is due to a single transgene, a skilled person can reproduce the invention from a living sample. If, instead, the claimed trait is dependent on a large number of structurally undefined loci in the genome, these will segregate in subsequent generations and it will be an undue burden to reproduce the invention from the deposited sample (T 1957/14).
(2) By disclosing in the application as filed the gene sequence responsible for the claimed trait together with instructions on how to reproducibly introduce by technical means such an altered sequence in a target organism (e.g. by CRISPR-Cas).
If a technical feature of a claimed plant or animal, e.g. a single nucleotide exchange in the genome, might be the result of either a technical

intervention (e.g. directed mutagenesis) or an essentially biological process (a natural allele), a disclaimer is necessary to delimit the claimed subject-matter to the technically produced product in order to comply with the requirements of Art. 53(b) and Rule 28(2). Otherwise the subject-matter is directed to excluded subject-matter and is to be refused on the basis of Art. 53(b) in conjunction with Rule 28(2). A disclaimer is required in all cases and, in particular, even if the description only mentions a technical method of production and is silent on the use of an essentially biological process. If, on the other hand, the feature in question can unambiguously be obtained by technical intervention only, e.g. a transgene, no disclaimer is necessary.
This should apply also if such a disclaimer relates to subject-matter that was not disclosed in the application as filed. In such a case the disclaimer fulfils the requirements laid down in G 1/03, G 2/03 and G 1/16 because it is introduced to exclude subject-matter not eligible for patent protection (for the general principles governing disclaimers see also H-V, 4).
Such a disclaimer will only be necessary for patent applications with a filing date and/or a priority date after 1 July 2017. A disclaimer will not be required for patents granted before that date or for pending patent applications with a filing date and/or a priority date before 1 July 2017 (see G 3/19, OJ EPO 2020, A119).
The technicality of a claimed plant or animal product may lie in a non-heritable physical feature imparted directly to the claimed organism, e.g. a seed coated with a beneficial chemical.
The technical method of production of the plant or animal may be included in the claims, in the form of product-by-process claims (see F-IV, 4.12).
Plant products that are not propagation material, such as flour, sugars or

fatty acids, have to be considered on the basis of their chemical properties only. Thus provided the general patentability requirements are fulfilled, it will not be relevant whether the subject-matter (e.g. a sugar molecule) is isolated from a product (e.g. a living plant) of an essentially biological process or is produced in a laboratory.
Examples are provided below under G-II, 5.4.2.1.
This exclusion regarding plants and animals exclusively obtained by means of an essentially biological process does not apply to patents granted before 1 July 2017 or to pending patent applications with a filing date and/or a priority date before 1 July 2017 (see G 3/19, OJ EPO 2020, A119). For these applications and these granted patents, the exclusion from patentability of essentially biological processes for the production of plants does not have a negative effect on the allowability of a product claim directed to plants or plant material such as seeds or other plant propagation material. This applies even if the only method available at the filing date for generating the claimed plants or plant material is an essentially biological process for the production of plants, and also if the claimed product is

defined in terms of such a process (product-by-process claim, see F-IV, 4.12). In this context it is of no relevance that the protection conferred by the product claim encompasses the generation of the claimed product by means of an essentially biological process for the production of plants (see G 2/12 and G 2/13). The same principle applies *mutatis mutandis* with regard to animals produced by means of essentially biological processes (see also F-IV, 4.12).

5.4.1 Plant varieties

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. The method for 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). Therefore, plant varieties containing genes introduced into an ancestral plant by recombinant gene technology are excluded from patentability (G 1/98). However, if the invention concerns plants or animals, which are not exclusively obtained by means of an essentially biological process (see G-II, 5.4, above and G 3/19), 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).
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), which is not exclusively essentially biological, is not *a priori* excluded from patentability merely because the resulting product constitutes or may constitute a plant variety.

Controlled hybrids with inbred parents are excluded from patentability under Article 53(b), as they define either a seed or a plant which necessarily belongs to a particular plant grouping within the meaning of plant variety pursuant to Rule 26(4).
A claim cannot escape the exclusion of plant varieties under Article 53(b) by consisting of a large number of varieties, not even if there are hundreds of them. Only if the subject-matter of the claim comprises at least one embodiment which does not constitute a variety is the claim allowable under Art. 53(b) (see T 1208/12). For instance, a claim directed to a hybrid of a specific deposited Brassica variety with any high-yielding Brassica variety results in a Brassica hybrid variety, which is not patentable.

5.4.2 Essentially biological processes for the production of plants or animals

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. This applies even if the process comprises human intervention, including the provision of technical means, serving to enable or assist the
Rule 26(4)
Rule 27(b)
Rule 28(2)
Rule 26(5)

performance of the process steps or 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, interbreeding, 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 excluded from patentability.
Also selfing of a transgenic plant is excluded from patentability, as selfing, like crossing, is the mixing of entire genomes. These methods remain essentially biological and thus excluded from patentability even if they contain an additional feature of a technical nature, for example the use of genetic molecular markers to select either parent or progeny. Patent protection is available for any such additional technical steps *per se* which are performed either before or after the process of crossing and selection. However, such steps are ignored when determining whether or not the process as a whole is excluded from patentability under Article 53(b) EPC (see G 1/08, G 2/07).
However, if a process of sexual crossing and selection includes within it an additional step of a technical nature, which step by itself introduces a trait into the genome or modifies a trait in the genome of the plant produced, so that the introduction or modification of that trait is not the result of the mixing of the genes of the plants chosen for sexual crossing, then such a

process is not excluded from patentability under Art. 53(b) but qualifies as a potentially patentable technical teaching (see G 1/08, G 2/07).
Genetic engineering techniques applied to plants which techniques differ profoundly from conventional breeding techniques as they work primarily through the purposeful insertion and/or modification of one or more genes in a plant are patentable (see T 356/93). However, in such cases the claims must not, explicitly or implicitly, include the sexual crossing and selection process.
Processes for selecting plants or animals using genetic molecular markers without crossing the plants or animals are not excluded from patentability. Technical means, such as genetic molecular markers, used in such processes are not excluded, either.
A process for producing triploid seedless melon fruit which involves the pollination of sterile female flowers of a triploid plant, unable to carry out successful meiosis, with pollen of the diploid polliniser plant and which therefore does not concern sexually crossing two whole genomes of plants (implying meiosis and fertilisation) and the subsequent selection of plants is not an essentially biological process and is hence not excluded from patentability (T 1729/06).
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).
Claims to breeding methods leaving out an explicit reference to either a crossing or selection step, but where such a step is an essential feature, lack clarity and support (Art. 84).
The abbreviation NBT stands for "new breeding techniques". This is not a technical term, but a general one which is used for a variety of methods, some clearly technical but others either comprising or consisting of essentially biological processes. Therefore it is not suitable to differentiate whether claimed subject-matter is allowable under Article 53(b) and has no relevance in terms of patentability.

5.4.2.1 Examples

The following subject-matter relates to essentially biological processes excluded from patentability:
– Method for the production of plants having trait X comprising crossing plants A and B and selecting progeny having marker X.
– Use of a (transgenic) plant for generating further plants by crossing and selection.
– Use of a (transgenic) animal for breeding.

– Introgression of a (transgenic) gene X into a plant, i.e. introducing it into the genome by crossing and selection.
– Methods for plant breeding by crossing of whole genomes and selection of plants comprising the step of embryo rescue.
The following subject-matter relates to products exclusively obtained by means of an essentially biological process excluded from patentability and having a filing date or priority date after 1 July 2017 (see G 3/19):
– A plant produced by introgression of gene A, i.e. by introducing it into the genome by crossing and selection.
– A plant produced exclusively by crossing and selection, wherein molecular markers are used to assist the selection process.
– A plant part obtained exclusively by means of an essentially biological process which is propagation material, e.g. a seed or plant embryo.
– A cultivated pepper plant expressing a mutant AHAS enzyme
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The following subject-matter is not excluded from patentability under Art. 53(b):
– Method of producing a (transgenic) plant having trait X comprising introducing by transformation a vector comprising the sequence of SEQ ID NO: 1.
– Method for selecting animals having phenotype Y by screening for the presence of a marker having the sequence shown in SEQ ID NO: 1.
– Use of the nucleic acid of SEQ ID NO: 1 to select a plant having trait X.
– A mutant of a plant carrying a heritable exchange in a nucleotide sequence effected by technical means, e.g. UV mutagenesis or CRISPR/Cas with the proviso that the plant is not exclusively obtained by means of an essentially biological process (EBP).
– A transgenic plant carrying transgene X.
– Progeny of a mutant (wherein the mutant is not exclusively produced by EBP) or a transgenic plant which carries the mutation/the transgene.
– A seed of a wild-type plant covered with a chemical which inhibits fungal growth.
– Flour or oil produced from plant X (even if it is apparent from the description that said plant was exclusively obtained by means of an essentially biological method).

5.5 Microbiological processes

5.5.1 General remarks

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.
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
Art. 53(b)
Rule 26(6)
Rule 27(c)

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. Isolated plant or animal cells or in vitro plant or animal cell cultures are treated as microorganisms, since cells are comparable to unicellular organisms (G 1/98, 5.2).
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.
However, plant cells or tissues are usually totipotent and are able to regenerate the full plant. Therefore, even if plant cells or cell cultures may be regarded as the product of a microbiological process, plant material which is able to propagate the full plant is excluded from patentability if the plant from which the material originates has been exclusively produced by an essentially biological process (G 3/19) (for the meaning of the term "exclusively" in relation, for example, to offspring of transgenic organisms or mutants, see G-II, 5.4). Said exclusion does not apply to patents granted before 1 July 2017 nor to pending patent applications with a filing date and/or a priority date before 1 July 2017 (see G 3/19, XXIX).

5.5.2 Repeatability of results of microbiological processes

In the case of microbiological processes, particular regard has to 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.

5.6 Antibodies

5.6.1 General remarks

Antibodies exist in a number of different formats. The most frequently used format is an immunoglobulin G (IgG), which is a large, Y-shaped protein composed of two identical light chains and two identical heavy chains, both

containing variable and constant domains. Antibodies bind specifically to antigen targets via the antigen binding region which contains complementarity-determining regions (CDRs). In the case of an IgG, the antigen binding region consists of a heavy and light chain variable domain, each variable domain having three CDRs.
Other immunoglobulin structures are also known, such as heavy-chain-only antibodies that consist of only two identical heavy chains (with variable and constant domains) and the antigen-binding region consists of a single variable domain with only three CDRs.
Furthermore, knowledge of the structure-function relationships of parts of the antibody has allowed for the creation of antibody derivatives for a multitude of applications. These include antibody fragments, bispecific or multispecific antibodies and antibody fusion products.
Rule 33(1)
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In general, antibodies can be defined by (but are not limited to):
(a) their own structure (amino acid sequences);
(b) nucleic acid sequences encoding the antibody;
(c) reference to the target antigen;
(d) target antigen and further functional features;
(e) functional and structural features;
(f) the production process
(g) the epitope
(h) the hybridoma producing the antibody.

5.6.1.1 Definition by structure of the antibody

Since the three CDRs of each of the variable domains of the light and heavy chains of an IgG are normally responsible for binding to the antigen, the IgG, in order to be uniquely defined by its structure only and have its characteristic binding specificity, needs to be defined by the number of CDRs required for its binding to fulfil the requirements of Art. 84.
CDRs when not defined by their specific sequence must be defined according to a numbering scheme, for example, chosen from that of Kabat, Chothia or IMGT.
If an IgG is defined by fewer than the six sequences of its CDRs, the claim will be objected to under Art. 84 because it lacks an essential technical feature unless it is experimentally shown that one or more of the six CDRs do not interact with the target epitope or if it concerns a specific antibody format allowing for epitope recognition by fewer CDRs.

5.6.1.2 Definition by reference to the target antigen

An antibody can be functionally defined by the antigen it binds to, as long as the antigen is clearly defined in the claims. If the antigen is defined by a protein sequence, no sequence variability and no open language (e.g. an antigen comprising …) can be used in the definition of the antigen. Otherwise the subject-matter of the claim will be considered to lack novelty over any known antibody because existing antibodies will bind to the undefined region of the target antigen.

Examples of accepted antigen-defined antibody claim wording are:
– antibody binding to X;
– anti-X antibody;
– antibody reacting with X;
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– antibody specific for antigen X or
– antibody binding to antigen X consisting of the sequence defined by SEQ. ID. NO: y.
An antibody can also be defined by its ability to bind to a well-defined antigen in combination with a negative feature as for example: "Antibody binding to antigen X and not binding to antigen Y".

5.6.1.3 Definition by target antigen and further functional features

In addition to the functional definition by the antigen it binds to, claims directed to antibodies can be further characterised by functional features defining further properties of the antibodies; for example, the binding affinity, neutralising properties, induction of apoptosis, internalisation of receptors, inhibition or activation of receptors (c.f. e.g. T 299/86, Reasons 3 - 6, and T 1300/05, Reasons 4 - 7).
If an antibody is claimed exclusively by functional features and the prior art discloses in an enabling manner an antibody directed to the same antigen using an immunisation and screening protocol that arrives at antibodies having the claimed properties, it has to be assumed that the prior-art antibody inherently displays the same functional properties as the claimed antibody, which thus lacks novelty (cf. G-VI, 6). On the other hand, if the antibody is defined by unusual parameters, care has to be taken that these do not disguise a lack of novelty (F-IV, 4.11.1). In both these cases the burden of proof of novelty resides with the applicant.
If an antibody is defined exclusively by functional properties, it has to be carefully assessed whether the application provides an enabling disclosure across the whole scope claimed and whether the functional definition allows the skilled person to clearly determine the limits of the claim.

5.6.1.4 Definition by functional and structural features

Antibodies can also be defined by both functional properties and structural features. It is possible to claim an antibody characterised by the sequences of both variable domains or CDRs with less than 100% sequence identity when combined with a clear functional feature.

5.6.1.5 Definition by production process

Antibodies can be defined by the process of their production, i.e. either by the immunisation protocol of a non-human animal with a well-characterised antigen or by the specific cell line used to produce them; for more details see F-IV, 4.12.
However, such a product-by-process definition, based on the immunisation by an antigen comprising a sequence less than 100% identical to a defined sequence does not fulfil the requirements of Art. 84 because the use of variants renders the scope of the antibodies obtained by the immunisation process unclear.

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5.6.1.6 Definition by the epitope

An antibody may be defined also by its epitope, i.e. the set of specific amino acids of the antigen which are specifically recognised and bound by the antibody.

However, since an antibody defined in this way cannot be easily compared with known antibodies binding to the same antigen, the same principles as for the functional features apply (see G-II, 5.6.1.3).

If the epitope is a "linear epitope" (i.e. the antibody interacts with continuous amino acids on the antigen), it needs to be defined as a clearly limited fragment using closed wording (e.g. epitope consisting of).

If the epitope is "non-linear" or "discontinuous" (i.e. the antibody interacts with multiple, distinct segments from the primary amino-acid sequence of the antigen), the specific amino acid residues of the epitope need to be clearly identified.

The method for determining this discontinuous epitope must also be indicated in the claim and the application must provide an enabling disclosure allowing the skilled person to determine whether further antibodies bind this epitope. The application must also enable the production without undue burden of additional antibodies binding to the same epitope.

5.6.1.7 Definition by hybridoma

Antibodies may also be defined through a deposited hybridoma cell producing the antibodies. The general requirements for deposited biological materials apply, see F-III, 6.3.

5.6.2 Inventive step of antibodies

The subject-matter of a claim defining a novel, further antibody binding to a known antigen does not involve an inventive step unless a surprising technical effect is shown by the application or unless there was no reasonable expectation of success of obtaining antibodies having the required properties (see also G-VII, 13). Examples of surprising technical effects when compared to known and enabled antibodies are, for example, an improved affinity, an improved therapeutic activity, a reduced toxicity or immunogenicity, an unexpected species cross-reactivity or a new type of antibody format with proven binding activity.

If inventive step of a functionally defined antibody relies on an improved property versus the enabled antibodies of the prior art, the main characteristics of the method for determining the property must also be indicated in the claim or indicated by reference to the description (F-IV, 4.11.1).

If the surprising technical effect involves the binding affinity, the structural requirements for conventional antibodies inherently reflecting this affinity must comprise the required CDRs and the framework regions because the framework regions also can influence the affinity (T 1628/16).

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If a novel antibody binds to the same antigen as known antibodies,

inventive step is not acknowledged solely on the basis that the novel antibody is structurally different from the known antibodies. Arriving at alternative antibodies exclusively by applying techniques known in the art is considered to be obvious to the skilled person. The fact that the structure of the thus obtained alternative antibodies, i.e. their amino acid sequences, is not predictable is not a reason for considering these antibodies as non-obvious (see T 605/14, section 24; T 187/04, section 11). Nevertheless, antibodies can be inventive if the application overcomes technical difficulties in generating or manufacturing the claimed antibodies.
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Chapter III – Industrial application

1. General remarks

"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" is 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. An objection could arise under Art. 57 only in so far 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 an objection is made under Art. 83 (see F-III, 3).

2. Method of testing

Methods of testing generally are 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)

"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 storeroom 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

In general it is required that the description of a European patent application must, 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

Art. 57
Rule 42(1)(f)
Rule 29(3)

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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.

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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 is to 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, G-IV, 3 to 6, 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).

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.

A written description, i.e. a document, is 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 needs to 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 the application and any further investigation does not produce evidence sufficient to remove that doubt, the examiner does 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

Art. 54(1) and (2)
Art. 52(1)

(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 starts with the assumption that the document gives a true account of the earlier lecture, display or other event and therefore regards 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 does not pursue the matter further.

2. Enabling disclosure

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 is sufficient to enable the skilled person, at the relevant date (see G-VI, 3) and taking into account the common general knowledge in the field at that time, to practise the technical teaching which is the subject of the disclosure (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

The "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). Different claims, or

alternative subject-matters 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). 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 subject-matter encompassed by the same claim because it has an earlier effective date.

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 document when requested in accordance with Rule 53(3) (see A-III, 6.8 and subsections).

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 must not) be concerned 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.
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, 2.2.3).

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 needs to consider whether, in the light of these reasons and of the other prior art available, it is justified to pursue the matter. If so, the examiner must obtain a translation of the document (or merely the relevant part of it if that can be easily identified). If, after the translation, the document remains relevant, the examiner sends a copy of the translation to the applicant with the next official communication.
The requirement to provide a translation of a document in a non-official language also applies if the applicant is proficient in the language concerned. The translation enables the boards of appeal to examine whether the examining division's decision was justified (T 655/13).
Rule 56
Rule 58
Part G – Chapter IV-4 Guidelines for Examination in the EPO March 2022

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 is sent to the applicant (see B-X, 9.1.3). If only part of the translated document is relevant, the particular passage relied upon must 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 must 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)

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 in so far 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).

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

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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 validly 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 checks 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 temporarily deals 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

The above principles also apply to PCT applications designating EP, but with an important difference. Art. 153(5), in conjunction with Rule 165, makes it clear that a PCT application is included in the state of the art for the purposes of Art. 54(3) if 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).
Therefore, it is not required that all conditions for entry into the European phase be fulfilled for a Euro-PCT application to be considered a conflicting European application under Art. 54(3) EPC.

5.3 Commonly designated states

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

5.4 Double patenting

As acknowledged by the Enlarged Board, the prohibition on double patenting is applicable under Art. 125 (G 4/19). It is a principle of

procedural law generally recognised in the contracting states that two patents cannot be granted to the same applicant for the same subject-matter.
The prohibition of double patenting applies to three types of combinations of European applications by the same applicant: two applications filed on the same day, parent and divisional applications, or an application and its priority application.
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).In cases where there are two or more European applications from the same applicant designating the same state or states and the claims of those applications have the same filing or priority date and relate to the same invention, the applicant should be required to perform one of the following: 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 withdraw overlapping designations, or choose which one of those applications is to proceed to grant. If the applicant 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 (G 4/19). 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.
Art. 153
Rule 165
March 2022 Guidelines for Examination in the EPO Part G – Chapter IV-7
6. Conflict with national rights of earlier date
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, that designation may be withdrawn from the application for the contracting state of the national right of earlier date. Second, for such state, the applicant may file claims which are different from the claims for the other designated states (see H-II, 3.3 and H-III, 4.4). Third, the applicant can limit the existing set of claims in such a manner that the national right of earlier date is no longer relevant.
In opposition or limitation proceedings, the proprietor may file claims which are different from the claims for the other contracting states or limit the existing set of claims in such a manner that the national right of earlier date is no longer relevant (see H-III, 4.4 and D-X, 10.1).
In opposition proceedings, the proprietor may also request the revocation of the patent for the contracting state of the national right of earlier date (see D-I, 3; D-VIII, 1.2.5; E-VIII, 8.4). However, this is not possible in limitation or revocation proceedings (see D-X, 3).
Amendment of the application to take account of prior national rights is neither required nor suggested (see also H-III, 4.4). However, if the claims have been amended, then amendment of the description and drawings is

required if necessary to avoid confusion.

7. State of the art made available to the public "by means of a written or oral description, 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 online media platforms.

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. They may rarely arise in examination proceedings.

Rule 138

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7.2 Matters to be determined by the division as regards prior 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 (prior use), the 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 available, e.g. documents confirming sale, or affidavits related to the prior use, the 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, and if the prior use is not contested, the division may take a decision using the submissions and the evidence already available. If the prior use or certain circumstances relating to it are contested, the division will need to take further evidence (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. According to the circumstances of a particular case, such further evidence might have to be submitted by the party(ies). Evidence is always taken under participation of the party(ies), normally in oral proceedings. For details concerning means of evidence see E-IV, 1.2.

7.2.1 General principles

Subject-matter is 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). T 1833/14 contains an example where a commercially available product was found by the board not to have been made available to the public as the skilled person was not able to reproduce it without undue burden, i.e. the alleged public prior use did not amount to an enabling disclosure.

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.

In order to establish whether there is a tacit agreement, the division must consider the particular circumstances of the case especially whether one or more parties involved in the prior use had an objectively recognisable interest in maintaining secrecy. If only some of the parties had such an interest, it must be established if the other parties implicitly accepted to act accordingly. For example, this is the case when the other parties could be expected to maintain secrecy in accordance with the usual business practice in the relevant industry. For establishing a tacit agreement important aspects to be considered are, *inter alia*, the commercial relationship between the parties and the exact object of the prior use. The following may be indicators of a tacit secrecy agreement: A parent company – subsidiary relationship, a relationship of good faith and trust, a joint venture, the delivery of test specimens. The following may be indicators of the absence of such an agreement: An ordinary commercial transaction, the sale of parts for serial production.
As a rule, the general standard "balance of probabilities" applies. However, if practically all evidence lies within the power of the party bearing the burden of proof, the facts must be proven beyond reasonable doubt. For example, an opponent alleging that subject-matter was made available without any express or tacit agreement on secrecy must substantiate and, if contested, convincingly prove the circumstances from which public availability can be derived (e.g. ordinary sale to a customer, parts supplied for serial production). The proprietor can challenge this by demonstrating inconsistencies and gaps in the chain of proof or by substantiating facts Part G – Chapter IV-10 Guidelines for Examination in the EPO March 2022 from which secrecy can be derived (e.g. joint development, samples for test purposes). If these elements lead to reasonable doubts as to public availability, public prior use has not been established.
For the particular case of a non-prejudicial disclosure arising from an evident abuse in relation to the applicant, see G-IV, 7.3.2 and 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

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, such as in the course of a conversation or a lecture or by means of television, podcast or sound reproduction equipment.

Art. 55(1)(a)

Art. 54(2)

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7.3.2 Non-prejudicial oral description

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 that party's legal predecessor. In determining whether evident abuse has occurred, note G-V, 3.

7.3.3 Matters to be determined by the 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)).

7.3.4 Standard of proof

Unlike a written document, the contents of which are fixed and can be read

again and again, an oral presentation is ephemeral. Therefore, the standard of proof for ascertaining the content of an oral disclosure is high. Whether the amount of evidence provided is sufficient to establish the content of the oral disclosure based on this standard of proof has to be evaluated on a case-by-case basis and depends on the quality of the evidence in each case. However, evidence from the lecturer alone usually does not provide a sufficient basis for determining the content of the oral disclosure.

7.4 State of the art made available to the public in writing and/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 is not 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 must 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 actual person who delivered the talk 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).

In opposition, if the publication date of a document originating from the opponent is in dispute, the opponent must prove that date beyond reasonable doubt. However, if the document is a brochure for advertising, it must be taken into account that such brochures are not normally kept secret for long after printing (T 2451/13, T 804/05, T 743/89).

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 are 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 are to 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, this disclosure will not be used further as prior art against the application unless the examiner is able to present further evidence to maintain the disputed publication date.

The later the examiner sets out to obtain such evidence, the more difficult it may become. The examiner has to judge 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 must 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 March 2022 Guidelines for Examination in the EPO Part G – Chapter IV-15 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, email 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 email 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, the examiner 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 are not to 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).

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(d) Indexing dates given to the web page by search engines (see also T 1961/13). 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 can 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 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, it may be cited in the search report as an "L" document. The search report and the written opinion must 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 must ensure that the right publication date is used, 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 March 2022 Guidelines for Examination in the EPO Part G – Chapter IV-17 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. for the applicant at the time of receipt of the search report). For non-persistent URLs, or if, for other reasons, it is considered prudent, the examiner indicates how that specific URL is arrived at 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 must be taken that the complete URL is clearly legible. The same applies to the relevant publication date on a web page.

It has to 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 must always indicate the date on which the web page was retrieved. When citing internet disclosures, the examiner must explain the prior-art status of the document, e.g.:

(i) how and where the publication date was obtained (for example, that the eight digits in the URL represent the date of archiving in the format yyyymmdd), and
(ii) 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 are 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 trade marks 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, 2.2.8).

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.
When a potential error is detected, three situations may arise depending on whether the skilled person, using general knowledge,

(i) can directly and unambiguously derive from the prior art document that it contains an error and what the only possible correction should be;
(ii) can directly and unambiguously derive from the prior art document that it contains an error, but is able to identify more than one possible correction; or
(iii) cannot directly and unambiguously derive from the prior art document that an error has occurred.
When assessing the relevance of a document to patentability,
in case (i), the disclosure is considered to contain the correction;
in case (ii), the disclosure of the passage containing the error is not taken into account;
in case (iii), the literal disclosure is taken into account as is.
For possible errors concerning compound records in online databases, see B-VI, 6.5. For non-enabling disclosures, see G-IV, 2.

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:
(i) an evident abuse in relation to the applicant or that party's legal predecessor – e.g. the invention was derived from the applicant or that party's legal predecessor and disclosed against their wish; or

(ii) the display of the invention by the applicant or that party's legal predecessor at an officially recognised international exhibition as defined in 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 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 the 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). This must be proven on the balance of probabilities (see T 436/92).

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(1)
Art. 55(1)(a)
Art. 55(1)(b)
Art. 55(2)
Rule 25

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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 is to be noted that in considering novelty (as distinct from inventive step; see G-VII, 6), 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). For the specific case of selection inventions see G-VI, 8.
Furthermore, any matter explicitly disclaimed (with the exception of disclaimers which exclude unworkable embodiments) and prior art acknowledged in a document, in so far 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.
An unclear term cannot be used to distinguish the invention from the prior art and is not allowable under Art. 84 (see F-IV, 4.6.1).

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-art document

In determining novelty, a prior-art document is to 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-art 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 is sufficient to enable the skilled person, 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 (see T 26/85, T 206/83 and T 491/99).
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Similarly, it is to 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 is to 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-art 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-art 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 is 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 must have regard to the guidance given in F-IV, 4.5 to 4.21. Particularly for claims directed to a physical entity, non-distinctive characteristics of a particular intended use are to be disregarded (see F-IV, 4.13.1). 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, are to be taken into account (see the example March 2022 Guidelines for Examination in the EPO Part G – Chapter VI-3 of a "mold for molten steel" in F-IV, 4.13.1). 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 First or further medical use of known products

Where a substance or composition is already known, it may still be patentable under Art. 54(4) if the known substance or composition was not previously disclosed for use in a method referred to in Art. 53(c).

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 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.

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

Where the subject-matter of a claim is rendered novel only by a new therapeutic use of a medicament, the claim may no longer have the format of a so-called "Swiss-type" claim as instituted by decision G 5/83 ("Use of a substance or composition X for the manufacture of a medicament for therapeutic application Z") if the application has a filing or earliest priority date of 29 January 2011 or later (see the Notice from the EPO dated 20 September 2010, OJ EPO 2010, 514).

Art. 82

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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)
Yes
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 is also to be noted that a mere pharmaceutical effect does not necessarily imply a therapeutic 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.
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A claim in the format of a Swiss-type claim is a purpose-related process claim, whereas a claim drafted in accordance with Art. 54(5) is a purpose-related product claim. Therefore, such claims have different categories. This has the following consequences:
(i) If a parent application has been granted with a Swiss-type claim, granting a patent on the basis of the purpose-related product claim in its divisional application would not lead to double patenting (T 13/14; see also G-IV, 5.4).
(ii) Since a claim to a particular physical activity (e.g. method, process, use) confers less protection than a claim to the physical entity *per se* (G 2/88, Reasons 5.1), a Swiss-type claim confers less protection than a claim formulated according to Art. 54(5). Therefore a change from a Swiss-type claim to a claim drafted in accordance with Art. 54(5) contravenes Art. 123(3) (T 1673/11; see also H-IV, 3.4).

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).
A product qualifies as a "substance or composition" in the sense of Art. 54(5) if it is the active agent or ingredient in the specific medical use and if the therapeutic effect can be ascribed to its chemical properties (see G 5/83 and T 1758/15). For example, consider a filler material which is injected between a first tissue targeted for radiation treatment and a second sensitive tissue which is desired to be protected from radiation. If the shielding effect of the filler material is achieved by a mere mechanical displacement of the sensitive tissue relative to the target tissue, due to the volume it occupies between the two tissues, the filler material qualifies as a device rather than a substance or composition. On the other hand, if the filler material produced a radiation-reducing effect on the sensitive tissue which could be attributed to its chemical properties, it would be considered as a "substance or composition" in the sense of Art. 54(5).

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).
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A claim directed to the further therapeutic use of a substance/composition must 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 must 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 must 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 independent claim is directed to a composition, the definition of the composition may be inserted before or after the term "for use". For example: "Composition comprising X for use in the therapy of Y" or "Composition for use in the therapy of Y comprising X".
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 must 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) are 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).

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... 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)).
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The following are examples of claims which would not be considered novel:
Example 1
Composition comprising X for use by topical treatment/application
It is assumed that a composition comprising X is already known in the prior art.
Reasons for objection: Since the claim fails to identify the specific therapeutic indication for X, the feature "for topical treatment/application" remains *de facto* purely illustrative and does not limit the scope of the claim to that specific application.
Furthermore, the term "topical treatment/application" does not necessarily relate to use in a method referred to in Art. 53(c) since it could refer to a cosmetic treatment. Consequently, the subject-matter of the claimed composition would be anticipated if said composition comprising X is already known in the prior art.
Example 2
Composition comprising X for use in therapy by topical administration
It is assumed that a composition comprising X is already known in the prior art for a medical use.
Reasons for objection: The mode of administration may be a critical factor in a medical treatment and has been considered as a limiting feature, but only in relation to a further (specific) medical indication (T 51/93). "Topical administration" specifies only the mode of delivery, but does not relate to any therapeutic effect obtained thereby. Consequently, since the claim fails to identify the specific therapeutic indication, the feature "by topical administration" is merely illustrative and not a restrictive technical feature capable of establishing novelty. The subject-matter of the claimed composition would thus be anticipated if said composition comprising X is already known in the prior art for any medical use.
Example 3
Product X for use in a method of contraception
Reasons for objection: Such a claim would not be considered novel over the disclosure of product X *per se* because pregnancy is not a disease. This claim can usually be reformulated as a method of contraception using product X. Reformulation may not be possible in so far as the contraception method involves the personal and private sphere, i.e. it does not fulfil the requirement of industrial application (T 74/93).
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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).
If the independent claim is directed to a composition, the definition of the composition may be inserted before or after the term "for use".
Purpose-related product claims which do not define a diagnostic use excluded from patentability under Art. 53(c) are 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)).
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7.1.4 Surgical uses pursuant to Art. 54(5)

A claim defining a second surgical use may read "Substance X/ Composition comprising X for use in a method of intracardiac catheterisation as a protector of blood vessel walls".
If the independent claim is directed to a composition, the definition of the composition may be inserted before or after the term "for use".
Purpose-related product claims which do not define a surgical use excluded from patentability under Art. 53(c) are 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 (T 2106/10). A suitable formulation may read:
Substance (X)
or
Composition
(comprising X)
(according to
claim #)
for use in the therapy
of disease Y
according to claim #
or
for use according to
claim #
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*.
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The claim would also lack novelty over prior art disclosing a composition comprising 5 mg X, or a first medical application thereof.
The claim must 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 is 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.
However, a feature of a step in a chemical process which merely serves to explain the technical effect obtained is not a functional technical feature which could render a claim novel over prior art which discloses the same process with the same step which provides the same effect, even if it does not comprise a corresponding indication of technical effect. It is rather considered to be a discovery (T 151/13).

8. Selection inventions

Selection inventions deal with the selection of individual elements, subsets, 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;
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(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 both of the following two criteria are satisfied (see T 261/15 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;
The meaning of "narrow" and "sufficiently far removed" has to be decided on a case by case basis.
(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 the cases discussed in (i) and (ii) above. 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. Matter that is "hidden" in a prior-art document, in the sense of being reconditely submerged rather than deliberately concealed, is not considered to have been made available to the public (see T 666/89).
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, would seriously contemplate applying the technical teaching of the prior-art document in the range of overlap. If it can be fairly assumed that the skilled person would do so, it must be concluded that no novelty exists. In T 1571/15, regarding an alloy defined by its composition, the skilled person would not seriously contemplate working in the area of overlap, despite it falling in the centre region of the ranges disclosed in the prior-art document, since said prior-art document contained a pointer to another region.
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 teaching, see T 12/90, point 2.6 of the Reasons. There is a new technical teaching if certain technical elements are new in comparison to the

prior-art disclosure. An example of a new technical element is 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.

The concept of "seriously contemplating" 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 (T 666/89).

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 is 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 applicants themselves provide test results in the applications, 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

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-VI) 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. 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" is presumed to be a skilled practitioner in the relevant field of technology who is possessed of average knowledge and ability (average skilled person). The person skilled in the art 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). The skilled person is also 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 been in possession of 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 the relevant technical field (see T 774/89 and T 817/95). The skilled person 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 is to 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).
Art. 56
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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). 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-solution approach

In order to assess inventive step in an objective and predictable manner, the so-called "**problem-solution approach**" is applied.
In the problem-solution approach, there are three main stages:

(i) determining the "closest prior art",
(ii) establishing the "objective technical problem" to be solved, and
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(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 must 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-solution approach to each of these starting points in turn, i.e. in respect of all these workable solutions.

However, applying the problem-solution approach from different starting points, e.g. from different prior-art documents, is only required if it has been convincingly shown that these documents are equally valid springboards. In particular in opposition proceedings the structure of the problem-solution approach is not that of a forum where the opponent can freely develop as many inventive step attacks as desired in the hope that one of said attacks has the chance of succeeding (T 320/15, Reasons 1.1.2).

In the event of refusal or revocation, it is sufficient to show on the basis of one relevant piece of prior art that the claimed subject-matter lacks an inventive step: 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.

As a consequence the applicant or proprietor cannot refute the argument that the claimed subject-matter lacks inventive step by submitting that a more promising springboard is available: a piece of prior art on the basis of which the claimed invention is considered non-obvious cannot be "closer" than a document on the basis of which the claimed invention appears obvious, because it is evident in this situation that the former does not represent the most promising springboard from which to arrive at the invention (T 1742/12, Reasons 6.5; T 824/05, Reasons 6.2).

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. The examiner must not make an artificial interpretation of the

closest prior art based on prior knowledge of the application (see also G-VII, 8).

In identifying the closest prior art, account is taken of what the applicant acknowledges in the description and claims to be known. Any such acknowledgement of known art is regarded by the examiner as being correct, unless the applicant states that a mistake was made (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 cannot support the presence of an 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. For the treatment of claims comprising technical and non-technical features, see G-VII, 5.4. The criteria for determining whether a feature, even if non-technical in isolation, contributes to producing a technical effect in the context of the invention are explained in G-II, 3 and subsections, for different types of subject-matter listed under Art. 52(2).

In the context of the problem-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 the 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 G-VII, 5.4 and G-VII, 5.4.1).

The expression "technical problem" is 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 is to 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).
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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 the skilled person **would have done** so because the prior art provided motivation to do so in the 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 is nevertheless 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 features

It is legitimate to have a mix of technical and non-technical features appearing in a claim, as is often the case with computer-implemented inventions. The non-technical features may even form a major part of the claimed subject-matter. However, in the light of Art. 52(1), (2) and (3), the presence of an inventive step under Art. 56 requires a non-obvious technical solution to a technical problem (T 641/00, T 1784/06).
When assessing the inventive step of such a mixed-type invention, all those features which contribute to the technical character of the invention are taken into account. These also include the features which, when taken in isolation, are non-technical, but do, in the context of the invention, contribute to producing a technical effect serving a technical purpose, thereby contributing to the technical character of the invention. However, features which do not contribute to the technical character of the invention cannot support the presence of an inventive step ("COMVIK approach", T 641/00, G 1/19). 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 (see G-II, 3 and subsections).
The problem-solution approach is applied to mixed-type inventions in such a way as to ensure that inventive step is not acknowledged on the basis of features not contributing to the technical character of the invention, while all those features which do contribute are properly identified and taken into account in the assessment. To this end, where the claim refers to an aim to be achieved in a non-technical field, this aim may legitimately appear in the formulation of the objective technical problem as part of the framework of the technical problem that is to be solved, in particular as a constraint that

has to be met (T 641/00; see step (iii)(c) below and G-VII, 5.4.1).
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The steps below outline the application of the problem-solution approach to mixed-type inventions following the COMVIK approach:
(i) The features which contribute to the technical character of the invention are determined on the basis of the technical effects achieved in the context of the invention (see G-II, 3.1 to 3.7).
(ii) A suitable starting point in the prior art is selected as the closest prior art with a focus on the features contributing to the technical character of the invention identified in step (i) (see G-VII, 5.1).
(iii) The differences from the closest prior art are identified. The technical effect(s) of these differences, in the context of the claim as a whole, is(are) determined in order to identify from these differences the features which make a technical contribution and those which do not.
(a) If there are no differences (not even a non-technical difference), an objection under Art. 54 is raised.
(b) If the differences do not make any technical contribution, an objection under Art. 56 is raised. The reasoning for the objection is that the subject-matter of a claim cannot be inventive if there is no technical contribution to the prior art.
(c) If the differences include features making a technical contribution, the following applies:
– The objective technical problem is formulated on the basis of the technical effect(s) achieved by these features. In addition, if the differences include features making no technical contribution, these features, or any non-technical effect achieved by the invention, may be used in the formulation of the objective technical problem as part of what is "given" to the skilled person, in particular as a constraint that has to be met (see G-VII, 5.4.1).
– If the claimed technical solution to the objective technical problem is obvious to the person skilled in the art, an objection under Art. 56 is raised.
Determination of the features contributing to the technical character of the invention should be performed for all claim features in step (i) (T 172/03, T 154/04). However, in practice, due to the complexity of this task, the examiner can normally perform the determination in step (i) on a first-glance basis only and perform the analysis at the beginning of step (iii) in a more detailed manner. In step (iii), the technical effects achieved by the differences over the selected closest prior art are determined. The extent to which the differences contribute to the technical character of the invention is analysed in relation to these technical effects. This analysis, limited to the differences, can be performed in a more detailed manner and on a more concrete basis than the one performed at step (i). It may therefore reveal
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that some features considered in step (i) at first glance as not contributing to the technical character of the invention do, on closer inspection, make such a contribution. The reverse situation is also possible. In such cases, the selection of the closest prior art in step (ii) might need to be revised.
When performing the analysis in steps (i) and (iii) above, care must be taken to avoid missing any features that might contribute to the technical character of the claimed subject-matter, in particular if the examiners reproduce their understanding of the subject-matter of the claim in their own words during the analysis (T 756/06).
The examples in G-VII, 5.4.2.1 to 5.4.2.5 illustrate the application of the COMVIK approach.

5.4.1 Formulation of the objective technical problem for claims comprising technical and non-technical features

The objective technical problem must be a technical problem which the skilled person in the particular technical field might have been asked to solve at the relevant date. It must not be formulated in such a way as to refer to matters of which the skilled person would only have become aware by knowledge of the solution claimed (G-VII, 5.2). In other words, the objective technical problem must be so formulated as not to contain pointers to the technical solution. However, this principle only applies to those features of the subject-matter claimed which contribute to the technical character of the invention and hence are part of the technical solution. Merely because some feature appears in the claim does not automatically exclude it from appearing in the formulation of the problem. In particular, where the claim refers to an aim to be achieved in a non-technical field, this aim may legitimately appear in the formulation of the problem as part of the framework of the technical problem that is to be solved, in particular as a constraint that has to be met (T 641/00).
In other words, the formulation of the objective technical problem may refer to features which do not make a technical contribution, or to any non-technical effect achieved by the invention, as a given framework within which the technical problem is posed, for example in the form of a requirements specification provided to the person skilled in a technical field.
The aim of formulating the technical problem according to these principles is to ensure that inventive step is acknowledged only on the basis of features which contribute to the technical character of the invention. The technical effects used for formulating the objective technical problem have to be derivable from the application as filed when considered in the light of the closest prior art. They must be achieved over the whole scope of the claim. A claim must therefore be limited in such a way that substantially all embodiments encompassed by the claim show these effects (G 1/19, G-VII, 5.2).
For technical effects which are not directly achieved by the claimed invention but are only "potential technical effects", see G-II, 3.3.2.
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Regarding technical effects arising from specific technical implementations

where the design of algorithms is motivated by technical considerations of the internal functioning of the computer, see G-II, 3.3.
In the case of claims directed to a technical implementation of a non-technical method or scheme, in particular of a business method or game rules, a modification to the underlying non-technical method or scheme aimed at circumventing a technical problem, rather than addressing this problem in an inherently technical way, is not considered to make a technical contribution over the prior art (T 258/03, T 414/12). Rather, such a solution constitutes a modification to the constraints given to the technically skilled person tasked with the implementation of the given non-technical method or scheme.
In such cases, consideration must be given to any further technical advantages or effects associated with the specific features of the technical implementation over and above the effects and advantages inherent in the underlying non-technical method or scheme. The latter are at best to be regarded as incidental to that implementation (T 1543/06). They do not qualify as technical effects for the purpose of defining the objective technical problem.
Example
In a game played online over a distributed computer system, the effect of reduction in network traffic obtained by reducing the maximum number of players cannot form the basis for formulating the objective technical problem. It is rather a direct consequence of changing the rules of the game, which is inherent in the non-technical scheme. The problem of network traffic reduction is not addressed by a technical solution but circumvented by the non-technical gaming solution offered. The feature defining the maximum number of players thus constitutes a given constraint which forms part of the non-technical scheme that the skilled person, e.g. a software engineer, would be tasked to implement. Whether the claimed specific technical implementation would have been obvious to the skilled person would still have to be assessed.

5.4.2 Examples of applying the COMVIK approach

The following examples aim at illustrating the application of the COMVIK approach using the steps listed in G-VII, 5.4 in various scenarios. The scenarios are adapted from case law. The claims are greatly simplified for illustrative purposes.

5.4.2.1 Example 1

Claim 1:
Method of facilitating shopping on a mobile device wherein:
(a) the user selects two or more products to be purchased;

(b) the mobile device transmits the selected products data and the device location to a server;
(c) the server accesses a database of vendors to identify vendors offering at least one of the selected products;
(d) the server determines, on the basis of the device location and the

identified vendors, an optimal shopping tour for purchasing the selected products by accessing a cache memory in which optimal shopping tours determined for previous requests are stored; and
(e) the server transmits the optimal shopping tour to the mobile device for displaying.
Application of the steps of the problem-solution approach according to G-VII, 5.4:
Step (i): The features contributing to the technical character are at first glance identified as a distributed system comprising a mobile device connected to a server computer which has a cache memory and is connected to a database.
Step (ii): Document D1, which discloses a method for facilitating shopping on a mobile device wherein the user selects a single product and the server determines from a database the vendor selling the selected product nearest to the user and transmits this information to the mobile device, is selected as the closest prior art.
Step (iii): The differences between the subject-matter of claim 1 and D1 are:
(1) The user can select two or more products to purchase (instead of a single product only).
(2) An "optimal shopping tour" for purchasing the two or more products is provided to the user.
(3) The optimal shopping tour is determined by the server by accessing a cache memory in which optimal shopping tours determined for previous requests are stored.
Differences (1) and (2) represent modifications of the underlying business concept, since they define producing an ordered list of shops to visit which sell these products. No technical purpose is served, and no technical effects can be identified from these differences. Hence, these features make no technical contribution over D1. On the other hand, difference (3) makes a technical contribution as it relates to the technical implementation of differences (1) and (2) and has the technical effect of enabling rapid determination of the optimal shopping tour by accessing previous requests which are stored in a cache memory.
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Step (iii)(c): The objective technical problem is to be formulated from the perspective of the person skilled in the art as an expert in a technical field (G-VII, 3). Such a person is not deemed to have any expertise in business-related matters. In the present case, the skilled person can be defined as an expert in information technology who gains knowledge of the business-related features (1) and (2) as part of the formulation of the technical problem to be solved, as would be the case in a realistic situation in the form of a requirement specification. The objective technical problem is thus formulated as how to modify the method of D1 to implement in a technically efficient manner the non-technical business concept defined by the differences (1) and (2), which is given as a constraint to be met.

Obviousness: Following requirement (1), it would have been a matter of routine for the skilled person to adapt the mobile device used in D1 so as to enable the user to select two or more products instead of a single one. It would also have been obvious to assign the task of determining the optimal shopping tour (arising from requirement (2)) to the server, by analogy with the server likewise determining the nearest vendor in D1. Since the objective technical problem further requires a technically efficient implementation, the skilled person would have looked for efficient technical implementations of the determination of a tour. A second document D2 discloses a travel planning system for determining travel trips, listing a set of places to visit, and addresses this technical problem: the system of D2 accesses for this purpose a cache memory storing results of previous queries. The skilled person would thus have considered the teaching of D2 and adapted the server in D1 to access and use a cache memory as suggested in D2 so as to provide a technically efficient implementation of the determination of the optimal shopping tour, i.e. difference (3). Hence, no inventive step is involved within the meaning of Art. 52(1) and 56.
Remarks: The example shows a typical application of the approach developed in T 641/00 (COMVIK). The analysis of technical effects is performed in detail at step (iii) to see if the differences from the closest prior art comprise features making a technical contribution. This analysis refines the initial finding of step (i) by identifying the feature of accessing the cache memory for results of previous requests in the step of determining the tour as a technical feature. Note that in this case step (i) would not need to be indicated explicitly in the reasoning. In step (iii)(c), the non-technical modifications to the business concept are given to the skilled person as a constraint to be met. Whether or not the new business concept is innovative is here irrelevant for the assessment of inventive step, which has to be based on the features of its technical implementation.

5.4.2.2 Example 2

Claim 1:

A computer-implemented method for brokering offers and demands in the field of transporting freight, comprising the following steps:
(a) receiving transportation offers/demands from users, including location and time data;

(b) receiving current location information of the users from GPS terminals with which the users are equipped;
(c) after receiving a new offer/demand request, verifying if there are previous offers/demands not yet satisfied that can respond to the new request;
(d) if so, selecting the one for which the current locations of both users are closest; and
(e) otherwise storing the new request.

Application of the steps of the problem-solution approach according to G-VII, 5.4:

Step (i): Underlying the claimed method is the following business method:
A method for brokering offers and demands in the field of freight transportation, comprising:
– receiving transportation offers/demands from users, including location and time data;
– receiving information regarding the current location of the users;
– after receiving a new offer/demand request, verifying if there are previous offers/demands not yet satisfied that can respond to the new request;
– if so, selecting the one for which the current locations of both users are closest; and
– otherwise storing the new request.
Such a business method is *per se* non-technical and excluded under Art. 52(2)(c) and (3). Brokering offers and demands is a typical business activity. Using the geographical location of users is the kind of criterion which a transportation broker could specify as part of a business method based on non-technical, business considerations only. This business method does not serve any technical purpose in the context of the invention and thus does not contribute to its technical character.
Therefore, only the features related to the technical implementation of this business method can be identified as the features contributing to the technical character of the invention:
– The business method steps are carried out by a computer.
– The current location information is received from GPS terminals.
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Step (ii): As a suitable starting point, document D1, which discloses a method of order management in which a server computer receives location information from GPS terminals, is selected as the closest prior art.
Step (iii): The difference between the subject-matter of claim 1 and D1 is thus the computer implementation of the steps of the business method defined above.
The technical effect of this difference is merely the automation of the business method underlying claim 1. The conclusion reached in step (i) holds, since the only distinguishing feature making a technical contribution is the technical implementation of this business method.
Step (iii)(c): The objective technical problem is formulated as how to adapt the method of D1 so as to implement the business method of brokering offers and demands according to the user's current location. The person skilled in the art is considered to be a software project team and is given the knowledge of the business method in the form of a requirement specification.
Obviousness: Adapting the method of D1 to execute the business method steps is straightforward and requires routine programming only. Therefore, no inventive step is involved within the meaning of Art. 52(1) and Art. 56.
Remarks: In this example, it was clear from the initial analysis at step (i) that underlying the claimed method was a method for brokering offers and

demands, which as such is a business method. The features defining the business method were easily separable from the technical features of its computer implementation. Therefore, this example illustrates a line of argument in which it was possible in step (i) to determine all the features which contribute to the technical character of the invention and all those which do not. This line of argument pertains more to the field of computer-implemented business methods and might be less suitable in other fields.

5.4.2.3 Example 3

This example illustrates the two-level technicality analysis set forth in section G-VII, 5.4.

Claim 1:

A system for the transmission of a broadcast media channel to a remote client over a data connection, said system including:

(a) means for storing an identifier of the remote client and an indication of an available data rate of the data connection to the remote client, said available data rate being lower than the maximum data rate for the data connection to the remote client;

(b) means for determining a rate at which data is to be transmitted based on the indication of the available data rate of the data connection; and

(c) means for transmitting data at the determined rate to said remote client.

Application of the steps of the problem-solution approach according to G-VII, 5.4:

Step (i): At first glance, all features appear to contribute to the technical character of the invention.

Step (ii): Document D1, which discloses a system for broadcasting video over an xDSL connection to the set-top boxes of subscribers, is selected as the closest prior art. The system comprises a database storing identifiers of subscribers' computers and, in association with them, an indication of the maximum data rate for the data connection to each subscriber's computer. The system further comprises means for transmitting the video to a subscriber's computer at the maximum data rate stored for said computer.

Step (iii): The differences between the subject-matter of claim 1 and D1 are:

(1) Storing an indication of an available data rate of the data connection to the remote client, said available data rate being lower than the maximum data rate for the data connection to the remote client.

(2) Using said available data rate to determine the rate at which the data is transmitted to the remote client (instead of transmitting the data at the maximum data rate stored for said remote client as in D1).

The purpose served by using an "available data rate" which is lower than a maximum data rate for the data connection to the remote client is not apparent from the claim. Therefore, the relevant disclosure in the

description is taken into account. In the description, it is explained that a pricing model is provided which allows a customer to choose from several service levels, each service level corresponding to an available data-rate option having a different price. A user may select an available data rate lower than the maximum data rate possible with the connection in order to pay less. Hence, using an available data rate which is lower than the maximum data rate for the connection to the remote client addresses the aim of allowing a customer to choose a data-rate service level according to that pricing model. This is not a technical aim, but an aim of a financial, administrative or commercial nature and thus falls under the exclusion of schemes, rules and methods for doing business in Art. 52(2)(c). It may thus be included in the formulation of the objective technical problem as a constraint to be met.
The features of *storing* the available data rate and of *using it to determine the rate at which the data is transmitted* have the technical effect of implementing this non-technical aim.
Step (iii)(c): The objective technical problem is therefore formulated as how to implement in the system of D1 a pricing model which allows the customer to choose a data-rate service level.
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Obviousness: Given the task of implementing this choice of data-rate service level in accordance with the pricing model, it would be obvious to the skilled person that the data rate purchased by a subscriber (i.e. the "available data rate" of claim 1), which can only be lower or equal to the maximum data rate of the data connection to the subscriber's computer (i.e. the "remote client" of claim 1), would have to be stored for each subscriber and used by the system to determine the rate at which data is to be transmitted to a subscriber. Therefore, no inventive step is involved within the meaning of Art. 52(1) and Art. 56.
Remarks: This example illustrates a claim which involves a complex mix of technical and non-technical features. On a first-glance basis in step (i), all features appeared to contribute to the technical character of the invention. After comparison with D1, a detailed analysis of the technical character of the contribution made by the invention over D1 was possible at step (iii). This detailed analysis revealed that the differentiating features addressed a non-technical aim. This non-technical aim could thus be incorporated into the formulation of the objective technical problem (T 641/00).

5.4.2.4 Example 4

Claim 1:
A computer-implemented method of determining areas in which there is an increased risk of condensation for a surface in a building comprising the steps of:
(a) controlling an infrared (IR) camera to capture an image of the temperature distribution of the surface;
(b) receiving mean values for the air temperature and the relative air humidity measured inside the building over the last 24 hours;

(c) calculating, based on said mean air temperature and mean relative air humidity, a condensation temperature at which there is a risk of condensation on the surface;
(d) comparing the temperature at each point on the image to said calculated condensation temperature;
(e) identifying the image points having a temperature lower than the calculated condensation temperature as areas at increased risk of condensation on the surface; and
(f) modifying the image by colouring the image points identified in step (e) in a particular colour to indicate the areas at increased risk of condensation to a user.
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Application of the steps of the problem-solution approach according to G-VII, 5.4:
Step (i): The control of an IR camera in step (a) clearly makes a technical contribution. The question is whether steps (b) to (f) also contribute to the technical character of the claimed subject-matter.
Considered in isolation, steps (b) to (e) relate to algorithmic/mathematical steps and step (f) defines a presentation of information. However, the claim is not directed to a mental act, a mathematical method or presentation of information as such (which would be excluded from patentability under Art. 52(2)(a), (c), (d) and (3)) because the claimed subject-matter involves technical means such as a computer.
Therefore, it has to be assessed whether the algorithmic and mathematical steps as well as the step related to presentation of information do, in the context of the invention, contribute to producing a technical effect, thereby contributing to the technical character of the invention.
Since the above-mentioned algorithmic and mathematical steps (b) to (e) are used to predict the physical state (condensation) of an existing real object (surface) from measurements of physical properties (IR image, measured air temperature and relative air humidity over time), they contribute to a technical effect serving a technical purpose. This applies regardless of what use is made of the output information about the risk of condensation on the surface (see G-II, 3.3, in particular subsection "Technical applications"). Thus, steps (b) to (e) contribute also to the technical character of the invention.
A decision on whether step (f) makes a technical contribution is deferred to step (iii) below.
Step (ii): Document D1 discloses a method for monitoring a surface to determine the risk of condensation forming on it. The risk of condensation is determined based on the difference of the temperature reading obtained via an IR pyrometer for a single point on the surface and the condensation temperature calculated based on the actual ambient air temperature and the relative air humidity. The numerical value of the difference is then shown to a user as an indication of the likelihood of condensation at said point. This document is taken as the closest prior art.

Step (iii): The differences between the subject-matter of claim 1 and D1 are:
(1) an *IR camera* is used (instead of the IR pyrometer of D1, which only captures the temperature at a single point of the surface);
(2) *mean* values for air temperature and relative air humidity measured inside the building *over the last 24 hours* are received;
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(3) the condensation temperature is calculated *on the basis of the mean air temperature and mean relative air humidity* and compared to the temperature at each point on the IR image of the surface;
(4) image points having a temperature lower than the calculated condensation temperature are identified as *areas* at increased risk of condensation on the surface;
(5) *colours* are used to indicate areas at increased risk of condensation.
As mentioned above, distinguishing features (1)-(4) contribute to the technical character of the claimed subject-matter and must be taken into consideration for the formulation of the technical problem. These features produce the technical effect of a more precise and reliable prediction of the risk of condensation as a result of considering all surface areas (as opposed to a single point) and accounting for temperature variations during a day.
Distinguishing feature (5) defines a particular manner of presenting information to a user (Art. 52(2)(d)) which does not produce a technical effect since any effect of the choice of displaying data using colours rather than numerical values depends on subjective preferences of the user: some users may prefer the former and other the latter (see G-II, 3.7). This feature thus does not make a technical contribution. It cannot support the presence of an inventive step and is not discussed further in the analysis since it has no bearing on the other distinguishing features.
Step (iii)(c): The objective technical problem is therefore formulated as how to determine the risk of condensation on a surface in a more precise and reliable manner.
Obviousness: The use of an IR camera for obtaining temperature readings on a surface can be considered a normal technical development in the field of thermography without exercising any inventive activity: IR cameras were well known at the effective date of the application. Using an IR camera is a straightforward alternative to measuring the temperature at several points on the monitored surface using an IR pyrometer for the skilled person to arrive at a temperature distribution of the surface.
However, D1 does not suggest considering a temperature distribution on a surface (as opposed to at a single point) and calculating mean values for air temperature and taking relative air humidity measured inside the building over the last 24 hours into consideration. Neither does it suggest taking into account different conditions which may realistically occur inside the building over time for predicting the risk of condensation.
Assuming that no other prior art suggests the technical solution of the

objective technical problem defined by distinguishing features (1)-(4), the subject-matter of claim 1 involves an inventive step.
Remarks: This example illustrates the situation addressed in G-VII, 5.4, second paragraph: features which, when taken in isolation, are
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non-technical but do, in the context of the claimed invention, contribute to producing a technical effect serving a technical purpose (features (b) to (e), which are algorithmic/mathematical steps). Since said features contribute to the technical character of the invention, they may support the presence of an inventive step.

5.4.2.5 Example 5

Claim 1:
A method for coating a workpiece using a thermal spray coating process, the method comprising:
(a) applying, using a spray jet, a material to the workpiece by thermal spray coating;
(b) monitoring the thermal spray coating process in real time by detecting properties of particles in the spray jet and supplying the properties as actual values;
(c) comparing the actual values with target values;
and, in the event that the actual values deviate from the target values,
(d) adjusting process parameters for the thermal spray coating process automatically by a controller on the basis of a neural network, said controller being a neuro-fuzzy controller which combines a neuralnetwork and fuzzy logic rules and thereby maps statistical relationships between input variables and output variables of the neuro-fuzzy controller.
Background: The invention relates to the control of an industrial process, i.e. thermal spray coating of a workpiece. The material used for the coating is injected with the help of a carrier gas into the high-temperature jet, where it is accelerated and/or molten. The properties of the resulting coatings are subject to great fluctuations, even with seemingly constant parameters of the coating operation. The spray jet is monitored visually with a CCD camera. The image picked up by the camera is sent to an image processing system, from which the properties of particles in the spray jet (e.g. velocity, temperature, size, etc) can be derived. A neuro-fuzzy controller is a mathematical algorithm which combines a neural network with fuzzy-logic rules.
Application of the steps of the problem-solution approach according to COMVIK:
Step (i): The method is directed at thermal spray coating, i.e. a specific technical process, comprising various concrete technical features, e.g. particles, workpiece, a spray coating device (implicit).
Step (ii): Document D1 discloses a method for the control of a thermal spray coating process by applying material to a workpiece using a spray jet,
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detecting deviations in the properties of the particles in said spray jet and adjusting process parameters automatically on the basis of the outcome of a neural network analysis. This document represents the closest prior art.
Step (iii): The difference between the method of claim 1 and D1 concerns the use of a neuro-fuzzy controller combining a neural network and fuzzy logic rules as specified in the second part of step (d).
Computational models and algorithms related to artificial intelligence are, on their own, of an abstract mathematical nature (G-II, 3.3.1). The feature of combining results of a neural network analysis and fuzzy logic defines a mathematical method when taken on its own. However, together with the feature of adjusting the process parameters, it contributes to the control of the coating process. Hence, the output of the mathematical method is directly used in the control of a specific technical process.
Control of a specific technical process is a technical application, see G-II, 3.3 (subsection "Technical applications"). In conclusion, the differentiating feature contributes to producing a technical effect serving a technical purpose and thereby contributes to the technical character of the invention. Therefore, it is taken into account in the assessment of inventive step.
Step (iii)(c): The objective technical problem must be derived from technical effects that are based on objectively established facts and that are directly and causally related to the technical features of the claim.
In the present case, the mere fact that the parameters are calculated using a combination of results of a neural network analysis and fuzzy logic – without any details on specific adaptation to the thermal spray coating process – cannot credibly ensure any technical effect beyond a different adjustment of the process parameters. In particular, no evidence can be found to acknowledge any increase in the quality of coating properties or of the thermal spraying method that would result from the combination of features of claim 1. In the absence of such evidence, the objective technical problem is to provide an alternative solution to the problem of adjusting the process parameters which control the thermal spray coating process which is already solved in D1.
Obviousness: Starting from the teaching of D1 and tasked with the above objective technical problem, the person skilled in the field of control engineering (G-VII, 3) would look for an alternative solution to determine the control parameters of the process.
A second prior-art document D2 discloses a combination of a neural network and fuzzy logic rules providing a neuro-fuzzy controller in the technical field of control engineering. From this prior art, it has become apparent that at the date of filing of the application, neuro-fuzzy controllers were well known and applied in the field of control engineering. The present solution is therefore considered to be an obvious alternative, rendering the subject-matter of claim 1 not inventive.
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Remarks: This example illustrates the case where a mathematical feature

which, when taken in isolation, is non-technical but contributes to producing a technical effect serving a technical purpose in the context of the claim. The feature of using a combination of neural network results and fuzzy logic for adjusting process parameters for controlling thermal spraying contributes to the technical character of the invention and may therefore support the presence of an inventive step.
However, in the present case, claim 1 does not contain any information about the coating properties to be achieved. The input and output variables of the neuro-fuzzy controller, how the controller is trained or how the output is used in the regulation of the process parameters are not defined. No features of the neuro-fuzzy controller are linked to any technical properties of the spray coating. The neuro-fuzzy controller is therefore not adapted for the specific application of thermal spray coating. There is no evidence of any particular technical effect which is credibly achieved over the whole claimed scope other than that of providing different process parameters as input to the controller.

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 also has 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 is not normally regarded as obvious;
(ii) whether the disclosures, e.g. documents, come from similar, neighbouring or remote technical fields (see G-VII, 3);
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(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

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 must be wary of *ex post facto* analysis of this kind. When combining documents cited in the search report, it always has to be borne 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 the examiner must attempt to visualise the overall state of the art confronting the skilled person before the applicant's contribution, and must seek to make a "real-life" assessment of this and other relevant factors. The examiner has to 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 has to be hesitant in pursuing an objection that such a claim lacks inventive step.

9. Origin of an invention

While the claim must 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

If an 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. The unexpected effect must be based on the characterising features of the invention, in combination with the known features of the claim. It cannot be based merely on features which are, in combination, already comprised in the prior art.

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). If the skilled person would have to choose from a range of possibilities, there is no one-way street situation and the unexpected effect may very well lead to the recognition of an inventive step.

The unexpected property or effect must be described in precise terms. A vague statement such as "The new compounds have shown unexpectedly good pharmaceutical properties" cannot support the presence of an inventive step.

However, the product or process does not have to be "better" than known products or processes. It is sufficient that the property or effect would not have been expected.

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 be either 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 subsets 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 must 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 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).

Decision T 261/15 confirmed that the requirement for a sub-range to represent a purposive selection is a matter of inventive step and not necessary for establishing novelty (see also G-VI, 8).

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13. Inventive step assessment in the field of biotechnology

In the field of biotechnology, obviousness is considered at hand not only

when results are clearly predictable, but also when there is a reasonable expectation of success. In order to render a solution obvious, it is sufficient to establish that the skilled person would have followed the teaching of the prior art with a reasonable expectation of success. Likewise, a mere "try and see" attitude in light of the closest prior art does not necessarily render the solution inventive.

On the other hand, a "reasonable expectation of success" is not to be confused with the "hope to succeed". If researchers are aware when embarking on their research that, in order to reach a technical solution, they will need not only technical skill but also the ability to make the right non-trivial decisions along the way, this cannot be regarded as a "reasonable expectation of success".

For the assessment of inventive step of antibodies, see G-II, 5.6.2.

14. 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 in so far as they provide a novel and inventive product (see T 119/82). However, 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.

15. 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 must 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-art 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-art 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.
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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 interrelationship.

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 persons skilled in the art would expect such compounds to possess, so that they are 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.