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Czech Republic

Inputs for the Preparation of a Study on the Sufficiency of Disclosure

According to Section 26 (2) of Act No 527/1990 Coll., on Inventions and Rationalisation Proposals, as amended, the invention must be disclosed in the patent application in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.

A 'person skilled in the art' refers to a hypothetical person with the qualifications usually required to solve similar tasks in a respective field of technology.

The invention must be disclosed in the patent application, in particular by examples of embodiments of the invention in the description, so clearly and completely that the person skilled in the art can reproduce it, if necessary, without the need for any further inventive activity. On the other hand, it is assumed that the person skilled in the art does not need to have specifically explained to him/her such details as may be considered to belong not only to the state of the art but also to the common general knowledge of the person skilled in the art.

The specific requirements for disclosure to ensure its clarity and completeness depend on the technological field to which the claimed invention pertains. However, there is an exception for inventions in the field of microbiology, in particular for biotechnological inventions involving biological materials to which third parties do not have direct access. These inventions cannot be disclosed practically in the application so that a person skilled in the art can carry them out.

Specifically for patent applications in the biotechnological field, Section 5 of the Act No 206/2000 Coll., on the protection of biotechnological inventions defines when the description of the invention in the patent application is considered sufficient. According to Paragraph 1 of this Section it is only if a) no later than the date from which the applicant has the right of priority, the biological material has been deposited with an international depository authority recognized under the Budapest Treaty, b) the patent application, as filed, contains relevant information on the characteristics of the deposited biological material available to the applicant, and c) the patent application states the name of the depository authority and the accession number of the respective deposit.

The rules for assessing the application whether the subject-matter is sufficiently disclosed in the description can be defined in a general manner. However, in practice, applications must always be assessed individually.

Inorganic and Organic Chemistry, Including Pharmaceuticals

In the case of chemicals, there must be a 'balance' between the sufficiency of disclosure of the invention in the patent application and wording of the subject matter. Pursuant to Section 8 of Decree No 550/1990 Coll., on the Procedure in Matters of Inventions and Industrial Designs the claims must be clear, concise and be supported by the description. Therefore, examples of embodiments should be chosen in order to cover the claimed scope of protection.

In the case of the Markush formula, clearly not every compound that would fall under this claim can be documented in examples. On the contrary, it is not possible that only one substituent is documented in the examples in case of a certain often wide range of substituents. Alternatively, in the case of a component content range in the composition, component contents approaching only one extreme range were given in the examples.

In such cases, where the claimed scope of protection is clearly disproportionate in view of the evidence in the examples, the Industrial Property Office of the Czech Republic (hereinafter referred to as 'Office')

requires a limitation of the scope of claims in proportion to the scope documented in the examples. We understand the notion 'proportionately' as an adjustment of the scope of protection to what has been demonstrated in the examples and at the same time supported by the arguments in the descriptive part of the patent specification. If the applicant limits the scope proportionately or explain why such a request is unjustified, the Office should reconsider its opposition.

On the other hand, the clarity of the subject-matter also needs to be examined. If a group, e.g., alkyl without defining the number of carbon atoms, is claimed in the application, as well as in the description, but only methyl is given in the example, then the objection to the non-sufficiency of disclosure, and thus requirement for restriction of the scope of protection, is appropriate.

If esters, ethers, salts, and N-oxides are subjects-matters of protection, they must be sufficiently defined, prepared, or tested. Exceptions are 'pharmaceutically acceptable salts', which are considered obvious to a person skilled in the art and their preparation/testing is generally not required.

As for stereoisomers, the Markush formula generally includes all possible forms. However, if protection is desired for a particular stereoisomeric form, its specific preparation/testing is required, including evidence of its advantage over other forms.

Pro-drugs need to be defined, even generally mentioned in the context of substance protection.

For polymorphic forms, crystalline forms, co-crystals, their preparation/testing is required as well as proof of preference over other forms (amorphous, other crystalline), including indication of spectrum/peak measurement parameters (wavelength, radiation source used, etc.).

Hydrates, solvates generally mentioned in the context of substance protection, as well as 'pharmaceutically acceptable salts', are considered obvious to a person skilled in the art, but as far as the protection of the hydrate/solvate form is concerned, its preparation/testing is required, including again demonstrating the benefit.

The new use of a known compound, formulated by the so-called second medical use claim, must be demonstrated by tests; in the case of non-medicinal products, evidence of such use is of course required.

Regarding the method of preparation, it is not enough to describe the process only in theory. It is necessary to specify process parameters such as temperature, pressure, yield, etc.

As for supplementary protection certificates, it is necessary to emphasize not only the well-defined scope of protection, but also the sufficiency of disclosure. In this respect, the Office follows the EUCJ judgments: see in particular the judgment C-493/12 (Eli Lilly), or C-650/17 (Royal Pharma - refers to the judgment in Teva case), C-322/10 (Medeva), C-121/17 (Teva), which relate to functionally defined claimed substances by description. In essence, all of them imply the need for a link between the more general solution in the claim and the specification in the description (e.g. the functional definition in the claim and the addition of a specific substance with the given function in the description).

Microorganisms

In the case of a newly isolated strain or a newly genetically modified micro-organism, etc., it is, of course, required that the biological material is deposited with an international depository body in accordance with Article 7 of the Budapest Treaty at the latest on the date of application. These can theoretically include cell lines, hybridomas, vectors, viruses, bacteriophages, genes, chromosomes, isolated DNA or RNA, etc.

In each case, the origin of the biological material must be stated, namely from where it was isolated, how it was isolated (or prepared), or where and how the genetic modification was made.

The actual morphology of the microorganism (whether it is shaped in rods (bacilli) or spheres (cocci)), etc.) is not essential. However, in any case the properties of the microorganism that are essential for its industrial applicability must be described. In this connection, the purpose of its use must be disclosed. It is not possible to grant a patent without potential industrial applicability.

If a gene or protein sequence, especially in case the sequence is long, is of the essential feature of the solution, a sequence listing in the currently valid WIPO standard must be attached.

The general requirement that the scope of protection in the claims is adequately supported by examples of embodiments also applies here.

Artificial Intelligence

The Office does not yet have its own established practice in the field of artificial intelligence due to the small number of applications and caselaw in this area. In patent proceedings, we follow the practice of the EPO in this field.