

Learning path for patent examiners

Sufficiency of disclosure: Advanced level

Version: May 2024



Introduction

This publication, "Sufficiency of disclosure, Advanced level", is part of the "Learning path for patent examiners" series edited and published by the European Patent Academy. The series is intended for patent examiners at national patent offices who are taking part in training organised by the European Patent Office (EPO). It is also freely available to the public for independent learning.

Topics covered include novelty, inventive step, clarity, unity of invention, sufficiency of disclosure, amendments and search. Also addressed are patenting issues specific to certain technical fields:

- patentability exceptions and exclusions in biotechnology
- assessment of novelty, inventive step, clarity, sufficiency of disclosure and unity of invention for chemical inventions
- the patentability of computer-implemented inventions, business methods, game rules, mathematics and its applications, presentations of information, graphical user interfaces and programs for computers
- claim formulation for computer-implemented inventions

Each publication focuses on one topic at entry, intermediate or advanced level. The explanations and examples are based on the European Patent Convention, the Guidelines for Examination in the EPO and selected decisions of the EPO's boards of appeal. References are made to the Patent Cooperation Treaty and its Regulations whenever appropriate.

The series will be revised annually to ensure it remains up to date.

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All references to natural persons are to be understood as applying to all genders.

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1. Learning objectives

Participants to this course will learn:

- When medical use claims are considered sufficiently disclosed.
- The requirements necessary to demonstrate insufficient disclosure.
- Know when the burden of proof rests with the patentee/opponent.
- Understand what to do with applications which contradict physical laws.
- Know when post-published documents can be used as evidence supporting sufficiency of disclosure.
- Understand the concept of "presumption of validity" with respect to Article 83 EPC.
- Know when to make clarity and sufficiency objections in the context of "parameters", "results-to-be-achieved" and "essential features".

2. Reproducibility of (medical) use claims

For a medical use claim to meet the requirements of <u>Article 83 EPC</u>, the patent must disclose that the "product to be made" is suitable for the claimed therapeutic application. A claimed therapeutic application can be proven by any evidence reflecting the therapeutic effect. The disclosure of experimental results in the application is not always required to establish sufficiency, in particular if the application discloses a plausible technical concept and there are no substantiated doubts that the claimed concept can be put into practice (T 950/13 citing T 578/06).

Examples

The opposed patent in <u>T.814/12</u> disclosed that agents that selectively inhibited PKNbeta gene expression also prevented tumour cells from spreading and growing. This demonstrated that these agents were suitable for treating metastatic cancer since cell spreading was a characteristic of metastasis.

Legal references:

CL Book II.C.7.2, T 814/12, T 609/02, T 950/13

3. Experimental evidence/plausibility

For an objection of insufficient disclosure to succeed, it must demonstrate "serious doubts substantiated by verifiable facts" (T 19/90, T 890/02).

In *inter partes* proceedings, the burden of proof is on an opponent to show on the balance of probabilities that a skilled person reading the patent and using their common general knowledge would be unable to perform the invention (T 182/89).

Examples

In $\underline{T.182/89}$ relating to a process for polymerising α -alkylstyrenes, it is stated that, to establish insufficiency, the burden of proof is on an opponent to establish on the balance of probabilities that a skilled reader of the patent using their common general knowledge would be unable to carry out the invention. A mere statement by an opponent that one example of a patent has been repeated

once "exactly as described" without obtaining exactly the described results as set out and claimed in the patent is inadequate to discharge that burden of proof.

Legal references:

T 609/02, T 491/08, T 19/90, T 890/02, T 182/89, CL Book II.C.7.2, CL Book II.C.9

4. Invention contradicts generally accepted scientific principles

If a claimed invention contradicts accepted physical laws, the disclosure must prove to a skilled person conversant with mainstream science and technology that the invention is feasible, the onus being on the applicant (for example cold nuclear fusion, T 541/96).

The application should contain all the details of the invention required for the effect to be achieved (T 541/96).

Examples

<u>T 541/96</u> related to a method for cold nuclear fusion. The board of appeal decided that the applicant had not shown that the technology had been proven. Furthermore, the technology was contrary to natural physical laws and the application did not contain all the details of the invention required for the effect to be achieved.

Legal references:

T 541/96, T 748/03, CL Book II.C.9.6

5. Serious doubts that the invention can be performed

For an objection of insufficient disclosure to succeed, it must demonstrate "serious doubts substantiated by verifiable facts" (T 19/90, T 890/02). If the examiner argues that the application lacks sufficient disclosure, the onus is on the applicant to establish that the invention can be performed and repeated over the whole of the claimed range (T 409/91, T 694/92).

Examples

In <u>T 19/90</u> (the onco-mouse), claim 1 concerned the incorporation of an activated oncogene sequence into the genome of non-human mammalian animals in general.

The claimed invention referred to all non-human mammalian animals whereas the invention described in the examples had been performed only on mice.

The examining division was not convinced that the invention as performed on mice could be successfully carried out by a skilled person on all other kinds of non-human mammals and refused the application on the ground that the claims were unrealistically broad. However, the mere fact that a claim is broad is not in itself a ground for finding that the application does not comply with the requirement for sufficient disclosure.

Only if there are serious doubts, substantiated by verifiable facts, may an application be objected to for being insufficiently disclosed.

6. Facts, evidence and arguments

As proof that an invention has been insufficiently disclosed, it is necessary for any attempt by the skilled person to repeat it to fail despite following the conditions in the examples. To prove insufficient disclosure, it must be shown that the method disclosed in the patent is unworkable. The same level of skill must be applied when the two questions of sufficient disclosure and inventive step are being considered for the same invention.

Examples

Claim 1 in <u>T.485/00</u> disclosed a "method for improving the optical properties of paper characterized by utilizing calcium carbonate having a blocky six-sided rhombohedral final crystal morphology, with a surface area of from about 3 to about 15 m²/g, an average discrete particle size of from about 0.2 to about 0.9 microns, wherein the discrete particles have an aspect ratio less than 2, and a particle size distribution such that at least about 60 weight percent of the particles lie within 50 percent of the equivalent discrete particle average spherical diameter, as a filler in papermaking".

The board held that the opponent/respondent had not shown that the description of the patent would not enable the skilled person to prepare and use calcium carbonates as specified in claim 1. Although the burden of proof rested with the respondent, it had not submitted evidence showing that by reproducing the preparation methods described in the examples of the patent in suit, and determining the surface area, average particle size and particle size distribution using the information disclosed in the patent and the known methods of measurement, the skilled person would not, without undue experimentation within the meaning of decision <u>T 32/85</u>, be able to obtain calcium carbonates having the characteristics stated in claim 1, and use them as filler in papermaking.

The board found that the invention had been sufficiently disclosed.

Legal references:

CL Book II.C.9, T 1062/98, T 485/00, T 45/09

7. Burden of proof

Although the burden of proof in the framework of sufficiency of disclosure as a rule lies with the party raising the objection, this principle does not apply to cases where the application as filed does not provide a single example or other technical information from which it is plausible that the claimed invention can be carried out. If there are doubts regarding performance of the invention during search/examination, the burden of proof rests with the applicant. At the opposition stage, the burden to prove insufficiency is on the opponents, who must show that they were unable to put the invention into practice despite making all reasonable efforts.

Examples

Claim 1 in T 63/06 read as follows:

"Method of fuel injection and ignition in an internal combustion engine with the steps of:

- introducing air into the combustion chamber (21) of the engine,
- injecting fuel with a fuel injection valve (2) into the combustion chamber (21) to form a fuel/airmixture and
- igniting the fuel/air-mixture with a spark plug (3), characterized in that
- the spark plug (3) is disposed in a central portion of the combustion chamber (21) near the fuel injection valve (2), a fuel jet flow B is injected into the combustion chamber (21) so as to pass by the spark plug (3) and generate flame kernels (40) having a size of 1 mm or more and in time of a small load when the accelerator pedal position a is small, the ignition is performed by the spark plug (3) being ignited within the fuel injection time period in which energy of the fuel jet flow B is available to disperse said flame kernels (40) in the combustion chamber (21), so that the flame kernels (40) are carried on the fuel jet flow B to increase the penetration force of the flame."

Since the patent did not give any information on how to generate flame kernels having a size of 1 mm or more, there was only a weak presumption that the invention was sufficiently disclosed. In cases such as these, the opponent can discharge its burden by arguing that common general knowledge would not enable the skilled person to put this feature into practice.

The patent proprietor then bears the burden to prove the contrary, i.e. that common general knowledge would indeed enable the skilled person to carry out the invention.

The board decided that the invention was insufficiently disclosed.

Legal references:

GL F-III, 4, CL Book III.G.5.1, CL Book II.C.9, T 63/06

8. Post-published documents

An application relates to a chemical process for making semiconductors. Examples in the application show that the process has a surprising effect at 20°C, 30°C and 200°C. A claim is directed to this process and specifies that it is to be carried out between 20°C and 1 000°C. The examiner finds a document published after the filing date of the application that demonstrates that the surprising/unexpected effect is lost above 500°C. Is the application sufficiently disclosed?

Yes, the application is sufficiently disclosed because post-published documents (documents published after the filing date of the application) can be used as evidence when deciding whether the invention was reproducible without undue burden at the priority date. T 994/95, T 157/03 and T 2197/09 are relevant case law. Note that sufficiency of disclosure must be established at the priority date of the application. Although the claimed effect is known to be lost above 500°C from the post-published document, this is a clarity matter (Article 84 EPC). Such an ambiguity in a claim only leads to an objection under Article 83 EPC if the whole scope of the claim is affected (because it is impossible to perform the invention at all). If only part of the scope of the claim is involved (as is the case here), an objection under Article 84 is appropriate.

Note: G 2/21, however, deals with the possibility of relying on a purported technical effect for inventive step, when the evidence, on which the effect rests, had not been public before the filing date of the patent in suit and was filed after that date. The discussion might therefore continue.

Examples

In <u>T 2197/09</u> relating to "a lithographic projection apparatus", a PhD thesis was used as a post-published document.

Legal references:

CL Book II.C.6.8, T 994/95, T 157/03, T 2197/09, G 2/21

9. Presumption of validity

In general, a patent application is presumed to relate to an invention which is disclosed in a manner sufficiently clear and complete for it to be carried out by a skilled person (T.491/08, T.63/06).

However, if the application gives no information on how a feature of the invention can be put into practice, there is only a weak presumption of sufficient disclosure, and the examiner can argue that common general knowledge would not enable the skilled person to put this feature into practice (T.63/06).

Examples

In <u>T 491/08</u> the board stated that there was a presumption that, in general, a patent application relates to an invention which is disclosed in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art. The weight of arguments and evidence required to rebut this presumption depended on the strength of that presumption.

A strong presumption required more substantial arguments and evidence than a weak one.

In <u>T 491/08</u> the application did not contain detailed information on how to put the invention into practice, so fewer substantial arguments and evidence were required.

Serious doubts whether the skilled person could carry out the invention as claimed were sufficient (T.63/06).

Considering the specification of the application and the disclosure in the prior art, the board of appeal did not agree that the objection under <u>Article 83 EPC</u> was based on hypothetical plausibility considerations only and not, as required by decision <u>T 19/90</u>, on "serious doubts, substantiated by verifiable facts".

Therefore, the board decided that the invention was sufficiently disclosed.

Legal references:

CL Book II.C.9.1, CL Book III.G.5.1, T 63/06, T 491/08

Lack of support regarding whole range claimed or end parts only – different implications

Ambiguity in a claim will lead to an objection under <u>Article 83 EPC</u> only if the whole scope of the claim is affected (because it is entirely impossible to perform the invention).

If only part of the scope of the claim is involved, an objection under <u>Article 84 EPC</u> (clarity) is appropriate (<u>T 608/07</u>). Where only a small part of the claimed range is supported and the rest of the range is impossible, this is a matter of sufficiency. But if only the ends of the claimed ranges are impossible, this is a matter of clarity.

Examples

<u>T 608/07</u> related to a polymerisation process. The issue of insufficiency arose through ambiguity (namely the definition of the term "molecular weight").

Although the board accepted that this kind of ambiguity might lead to an insufficiency objection, it pointed out that the ambiguity in that case also related to the scope of the claims, i.e. <u>Article 84 EPC</u>.

The board noted that since <u>Article 84 EPC</u> is not a ground for opposition, care must be taken to ensure that an insufficiency objection arising out of an ambiguity is not merely a hidden objection under <u>Article 84 EPC</u>.

The board stated that for insufficiency arising out of ambiguity, it was not enough to show that an ambiguity exists, e.g. at the edges of the claims; it would normally be necessary to show that the ambiguity deprives the person skilled in the art of the promise of the invention.

Legal references:

GL F-III, 11, GL F-IV, 4.6, CL Book II.C.8, T 608/07

11. Clarity of claims vs sufficiency of disclosure

Unclear parameters mean that the scope of the claim is not defined properly (this is a clarity matter). However, if the unclear parameters concern an essential feature and the skilled person is unable to carry out the invention, then the invention is insufficiently disclosed (<u>Article 83 EPC</u>).

On the other hand, if an "essential feature" is missing from the claims but disclosed in the description, the claims are not supported because claims can only be granted with this "essential feature" and a lack of clarity arises (Article 84 EPC).

Alternatively, if an "essential feature" is missing and not disclosed in the application, insufficiency arises; this cannot be remedied without adding subject-matter (<u>Article 123(2) EPC</u>), so the application will be refused.

Where the claims define the invention in terms of a "result to be achieved" but the objection can be overcome using the description, then examiners should raise a clarity objection. If the invention is

defined in the claims in terms of a "result to be achieved" but the objection cannot be overcome using the description, then the invention is insufficiently disclosed.

Similarly, if only a small part of the claimed range is supported but the rest of the range is impossible, an objection of insufficient disclosure should be raised. However, when only the ends of the claimed ranges are impossible, examiners should raise an objection for lack of clarity under <u>Article 84 EPC</u>.

Examples

In <u>T 593/09</u>, claim 1 defined a "polyethylene terephthalate resin covered metal sheet, wherein a biaxially oriented film consisting of polyethylene terephthalate having a low temperature crystallization [LTC] temperature ranging from 130 to 165°C is covered at least on one side of a metal sheet by heat bonding". The board decided as follows:

Since the LTC temperature strongly depends on the heating rate applied and in the absence of any knowledge of what heating rate to apply, the skilled person thus is not able to establish whether a given polyethylene terephthalate film has an LTC temperature as required according to the opposed patent to obtain the desired peel, permeation and impact resistance.

Hence, because of the unclear "heating rate" parameter, the crucial LTC temperature is so ill defined that the skilled person, when trying to carry out the invention on which the opposed patent is based, is left with having to test each individual polyethylene terephthalate as to its peel, permeation and impact resistance.

In view of the numerous polyethylene terephthalates with different properties on the market and the even greater number of polyethylene terephthalates which can be synthesised using e.g. different reaction conditions or catalysts, this amounts to an undue burden to solve the problem addressed in the opposed patent. Its teaching thus in effect is at most a suggestion to perform a research programme to identify suitable materials.

Hence, the invention was insufficiently disclosed.

Legal references:

CL Book II.C.8, GL F-III, 11, T 608/07

12. Beyond the course

You can deepen what you have learned during this course with the following further readings:

- Guidelines for Examination in the EPO F-III, Sufficiency of disclosure, sections 1 to 12.
- Case Law of the Boards of Appeal of the EPO, II.C. sections 1 to 9.

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Responsible for the content European Patent Academy academy@epo.org