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Learning path for patent examiners

Sufficiency of disclosure: chemical inventions: Intermediate level

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Introduction

This publication, "Sufficiency of disclosure: chemical inventions, Intermediate 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.

Disclaimer

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

Contents

Legal references

1. Learning objectives

Participants to this course will learn:

- The experimental evidence required for medical use claims.
- The importance of an invention being inherently possible to be carried out.
- The definition and the legal basis of the deposit of biological material
- The definition of parameters linked to sufficiency of disclosure.

2. Experimental evidence

A claim under Article 54(4) or (5) EPC has a technical effect as part of the claim (compound X for use in *treating disease Y*). The treatment of disease Y is the technical effect.

For a medical use claim to fulfil the requirement of sufficiency of disclosure (Article 83 EPC), the patent has to ***disclose the suitability for treating disease Y*** by way of *in vivo* or *in vitro* data.

Either the application has to provide suitable evidence for the claimed therapeutic effect ***or it must be derivable from*** the prior art or ***common general knowledge*** that the indicated therapeutic effect can be achieved (T609/02 , point 9)

Although sufficiency of disclosure does not necessitate examples and experimental results in the application – particularly if the application discloses a **plausible** technical concept and there are **no substantiated doubts about the claimed concept –** there must be sufficient technical information present at the time of filing to render it technically **plausible** for the skilled person that the claimed compounds can be applied for the claimed therapeutic use.

Post-published evidence may be taken into account, but only to back up the findings in the application in relation to the use of the compound(s) as a pharmaceutical.

"If the description of a patent specification provides no more than a vague indication of a possible medical use for a chemical compound yet to be identified, later more detailed evidence cannot be used to remedy the fundamental insufficiency of disclosure of such subject-matter" (headnote, T 609/02).

"Where a therapeutic application is claimed […] in the form of the use of a substance or composition for the manufacture of a medicament for a defined therapeutic application, attaining the claimed therapeutic effect is a functional technical feature of the claim. […] As a consequence, under Article 83 EPC, unless this is already known to the skilled person at the priority date, the application must disclose the suitability of the product to be manufactured for the claimed therapeutic application" (T 0491/08, point 8).

Examples

Claim 6 specifies:

"Steroid hormones binding to the receptor for AP-1-stimulation for treating AP-1-stimulated tumour formation, arthritis, asthma, allergies and rashes."

The patent specification provided no evidence at all of complex formation between the steroid hormone and the receptor regulating AP-1-stimulated transcription; no data was present to indicate that these hormones could have an impact on any of the listed specific diseases.

Post-published evidence clearly established the link between the steroid hormone of the patent and disruption of AP-1-stimulation of transcription, confirming that the diseases listed in the patent in suit were likely to be treated by said steroid hormone.

The post-published evidence was not accepted. Sufficiency of disclosure must be satisfied at the effective date of the patent, i.e. on the basis of the information in the patent application together with the common general knowledge then available to the skilled person.

At the time of filing, it was not known that the effect could be achieved by disrupting AP-1-stimulation of transcription using the steroid hormone receptor complex.

Since it was not known at the time of filing, the suitability for the therapeutic effect had required experimental evidence. The lack of plausibility could not be remedied afterwards.

Legal references:
Art. 83 EPC, CL Book II.C.7.2; CL Book II.C.9, T 609/02; T 491/08

3. Performance of invention contrary to laws of nature

An invention contrary to the laws of nature cannot be repeated or carried out by the skilled person. The successful performance of the invention therefore is inherently impossible.

Claims for any such invention directed to its function, and not merely to its structure, give rise to objections under Article 83 EPC, and possibly also under Article 52(1) EPC, because the invention is not "susceptible of industrial application".

An invention claiming to revolutionise the established foundation of science and technique faces a high burden of proof.

In *ex parte* proceedings, if an examining division objects that the description's disclosure is insufficient, the burden of proof is normally with the examining division.

If an invention is "revolutionary" or going against the common general knowledge (e.g. related to "water having a memory"), it may be justified to shift this burden of proof back to the applicant owing to the finding that the invention's feasibility and reproducibility do not appear sufficiently plausible on the basis of the disclosure. Doubts might arise, for example, merely because a technical effect that is ***a priori*** **contrary to the laws of physics** is not adequately substantiated by experimental results.

Examples

Claim 1: "A mixture of homeopathic dilutions C12 + C30 + C200 of polyclonal rabbit antibodies against the C-terminal fragment of the angiotensin II receptor for use in treating hypertension."

None of the three dilutions of the mixture referred to in the claim contained a single antibody molecule (homeopathic approach).

Angiotensin II receptor-binding antibodies are conventionally used for lowering blood pressure, i.e. for treating hypertension (conventional medicinal chemistry approach).

The invention went "against established laws of nature" in the sense that, as a result of the high homeopathic dilution, the mixture no longer reliably contained a single antibody that could bring about a therapeutic effect.

From a homeopathic point of view, the claim also went against the homeopathic theory that "like cures the like". The experimental disclosure in the patent was weak and could not establish that the effect (which was part of the claim: "use in treating hypertension") was achieved.

The application was refused for insufficient disclosure (T 1273/09).

Legal references:
Art. 83 EPC, GL F-III, 3, CL Book III.G.5.2.2, T 1842/06

4. Performance relies on chance or mere trial and error

Occasionally, applications are filed in which there is a fundamental insufficiency in the invention in the sense that it cannot be carried out by a person skilled in the art; this constitutes a failure to satisfy the requirements of Article 83 EPC, which is essentially irreparable.

This is the case where the successful performance of the invention is dependent on chance, i.e. when the skilled person following the instructions for carrying out the invention finds either that the alleged results of the invention are unrepeatable or that success in obtaining them is achieved in a totally unreliable way. Sufficiency of disclosure cannot be acknowledged if the skilled person has to carry out a research programme based on trial and error to reproduce the results of the invention, with limited chances of success (T 38/11, Reasons 2.6).

An example where this may arise is a microbiological process involving mutations.

Example: **T 727/95**

"Micro-organism designated Acetobacter and having the ability of micro-organisms [...]".

- The application discloses a cellulose high-producing mutant Acetobacter.
- This mutant in nature is a chance event with no guarantee that it can be successfully obtained again.
- Only the Acetobacter micro-organisms which are derived from the deposited micro-organism can be obtained without undue burden, but the claims are not limited to these.
- The claim is not repeatable without undue burden over the whole scope claimed, contrary to Article 83 EPC.

Legal references:
Art. 83 EPC, GL F-III, 3, CL Book II.C.6.7, CL Book II.C.7.4, T 38/11, T 105/14

5. Non-working embodiments

The fact that only variants of the invention, e.g. one of a number of its embodiments, are not capable of being performed does not immediately entail that the subject-matter of the invention as a whole is

incapable of being performed, i.e. incapable of solving the problem involved and therefore of achieving the desired technical result.

However, the relevant claims and the parts of the description relating to the variants of the invention which are incapable of being performed must then be either deleted or marked as background information that is not part of the invention (see Guidelines F-IV, 4.3(iii)) at the division's request if the deficiency is not remedied. The specification must then be so worded that the remaining claims are supported by the description and do not relate to embodiments which have proven to be incapable of being performed.

In some cases (for example claims relating to a combination of ranges or Markush claims), the scope of the claim might encompass a large number of alternatives, some of which correspond to non-working embodiments. In these cases, the presence of non-working embodiments in the claim is of no harm as long as the specification contains sufficient information on the relevant criteria to identify the working embodiments within the claimed alternatives (G 1/03).

Legal references:
Art. 83 EPC, GL F-III, 5.1

6. Biological material

In accordance with Rule 26(3) EPC, the term "biological material" means any material that contains genetic information and is capable of reproducing itself or being reproduced in a biological system.

The biological material has to be deposited if the words are not enough for the skilled person to carry out the invention concerning this biological material, or if the biological material is not publicly available. Sometimes the biological material is deposited as an insurance against a sequencing error.

Rule 31 EPC governs the deposit of biological material:

- Biological material which is not available to the public or cannot be described in a way that it can be carried out must be deposited with a recognised institution before the filing date.
- The published application must disclose the accession number of the biological material.

Legal provisions governing the deposit of biological material:

- Article 83 EPC: sufficiency of disclosure
- Rule 31 EPC: where deposited, mention in application (depositor = applicant)
- Rule 32 EPC: expert solution
- Rule 33 EPC: availability of sample
- Rule 34 EPC: new deposit

Legal references:
Art. 83 EPC, R. 31 EPC; R. 32 EPC; R. 33 EPC; R. 34 EPC, GL F-III, 6.1, R. 6.1 Budapest Treaty

7. Public availability of biological material

There are various items of case law on deposits as a source of public availability of biological material. The biological material must be readily available (either commercially or deposited in a recognised depositary institution).

- T 412/93 (see also T 542/95 and T 361/87): deposit may be best mode, but not necessary if invention is possible without it; long and laborious process not detrimental as long as success is certain.
- T 727/95: relying on chance events for reproducibility amounts to undue burden in the absence of evidence that such chance events occur and can be identified frequently enough to guarantee success (see point 11, obtaining further natural isolates). Point 8: mutants are OK if the deposit is available as the starting point.
- T 261/08, sufficiency of disclosure of micro-organisms which are not deposited: habitat must be identified; widespread presence of target micro-organism; or there is an enrichment and cultivation method by a simple test to screen for production of compound of interest or activity.

Examples

1. Baker's yeast is well known and commercially available; deposit not necessary for public availability
2. T 2068/11 – deposit necessary if the source of the micro-organism to be screened is large (e.g. milk from Japan)
3. T 549/05 – strain *Aspergillus niger 489* "isolated from soils of sugar cane regions of Brazil" not sufficiently disclosed in the absence of a deposit
4. T 2542/12 – Cod's syndrome pathogen: no indication where to start looking for infected fish, to re-isolate the micro-organism; no information on whether the disease was present in all cod farms along the Atlantic Ocean; cod farms are commercial entities – not freely accessible and not under any obligation to share their diseased fish with anybody asking for a sample

Legal references:

Art. 83 EPC, R. 31 EPC; R. 32 EPC; R. 33 EPC; R. 34 EPC, GL F-III, 6.2, CL Book II.C.7.6

8. Parameters and insufficient disclosure

Parameters are characteristic values of *measurable properties* (e.g. melting point, conductivity) or may take the form of *mathematical formulae of several variables*.

Claims using parameters are only *clear* if the parameters can be clearly and reliably determined. Claims are only *supported* if the method for determining the parameters is either common general knowledge or disclosed in detail in the description.

Parameters in claims therefore frequently lead to objections under Article 54, 84 or 83 or both 84 and 83 EPC. Whether the objection for ill-defined parameters is one under Article 84 or 83 EPC depends on whether the technical measures are necessary to solve the problem addressed (T 61/14).

Parameters in claims are problematic if the parameters are unusual or if the determination/measurement of the parameters is unclear or insufficiently disclosed and where a comparison with the prior art is thus difficult or impossible.

The consequence of a claim containing an ill-defined ("unclear", "ambiguous") parameter is that a person skilled in the art cannot know whether they are working within or outside the scope of the claim.

- They lead to an objection under Article 54 EPC if they make it impossible to compare the claim with the prior art.
- They lead to an objection under Article 84 EPC if the claim is not clear.
- They lead to an objection under Article 83 EPC if the way to determine the parameter is not sufficiently disclosed and if the value of the parameter is necessary to solve the problem addressed.

If the value of the parameter depends on the measurement method (e.g. viscosity), the measurement method must be part of the claim (e.g. "… where the viscosity is 12 cP (centipoise) determined at 25°C with a falling-ball viscosimeter").

Examples

Claim 1: A photocatalyst comprising titanium oxide and a second metal-containing compound on the surface thereof, wherein the photocatalyst has an index X of 0.2 or more calculated by equation X=B/A where A and B are integrated values of absorbance within a wavelength of from 220 nm to 800 nm and from 400 nm to 800 nm, respectively.

Claim 4 concerns a method of producing a catalyst according to claim 1.

The **prior art** discloses a photocatalyst produced according to a method falling under claim 4 and including all the features of claim 1 except parameter X, which is not known.

Index X is the parameter in the claim. It describes the proportion of the UV-visible light absorbed in the visible range; if it is below 0.2 there is very little absorbed and the product is almost white.

None of the documents in the proceedings mentions index X (i.e. the unusual parameter). There is no evidence that it is part of the common general knowledge or was already disclosed or used. The prior art uses a method that falls under the claimed method but does not describe the obtained product with "parameter X". Claim 1 cannot be clearly distinguished from the prior-art product (other than on account of the unusual parameter). The burden of proof is on the applicant to show that a difference exists. If the applicant cannot do so, claim 1 is held to be not novel over the prior art (T 1764/06).

Legal references:

Art. 54 EPC, Art. 83 EPC, Art. 84 EPC, GL F-III, 11, GL F-IV, 4.11, T 61/14

9. Beyond the course

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

- T 727/95
- Budapest treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure

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