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Learning path for patent examiners

Sufficiency of disclosure: chemical inventions: Advanced level

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Introduction

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

- To assess sufficiency of disclosure for hypothetical examples, medical uses and antibodies and how to consider post-published evidence
- The importance of filing sequence listings, when necessary

2. Hypothetical examples

The party challenging the disclosure usually bears the burden of proof. In some cases, the burden of proof is shifted:

- In T 792/00, the board found that if the patent contained only an example with a hypothetical experimental protocol, and if this example was to be relied on for showing sufficiency, then the burden of proving that this protocol worked in practice as stated lay with the patentee. Evidence that a variation of the protocol worked was unlikely to be enough.
- However, if the example contained a complete experimental protocol and the patentee affirmed that the results reported had been obtained, a board was likely to accept that the patentee had done enough to shift the burden of proof to the opponent, who would then have to provide a repeat of the experiment in order to convincingly demonstrate that the protocol did not, in fact, work as stated.

Legal references:
Art. 83 EPC, CL Book III.G.5.2.2

3. Level of disclosure for medical use: plausibility

Attaining a therapeutic effect in the medical indication recited in a purpose-related product claim **is a functional feature** of any such claim. If an invention lacks reproducibility because its desired technical effect as expressed in the claim is not achieved, this results in a lack of sufficient disclosure, which has to be objected to under Article 83 EPC. Therefore, to meet the requirements of Article 83 EPC, it **must be shown or rendered plausible** that **at the relevant date** (priority or filing date) said therapeutic effect was indeed achieved by the claimed compound in the disease recited in the claim in light of the skilled person's common general knowledge (T 609/02).

Hypothetical statements that studies "may be performed" and "effects may be observed" cannot establish the suitability of a compound for treating a disease.

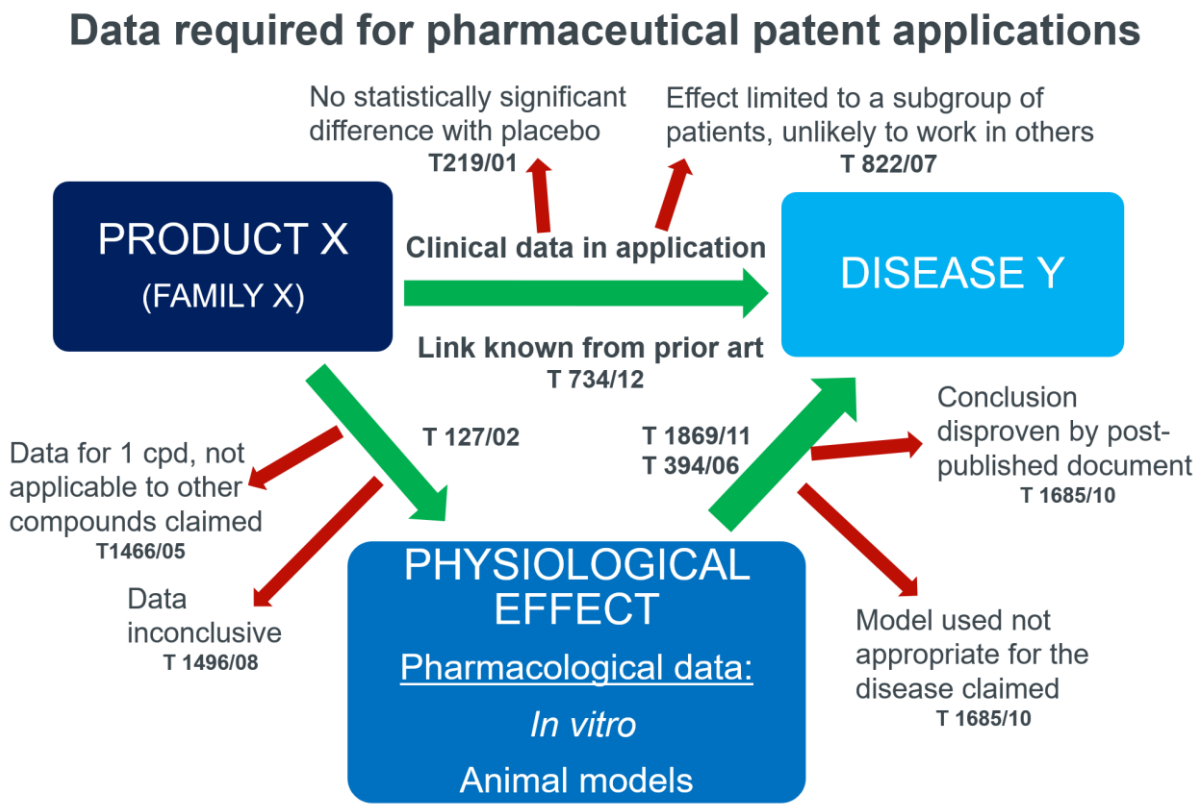
No clinical data are required. It is sufficient for it to be **plausible** that the biological pathway targeted by the compound plays a role in the disease at issue to provide a therapeutic effect. To this end, animal models (such as knock-out animals demonstrating the effect on biological pathways) and ***in vitro* data may be sufficient**.

Even in the absence of experimental results, no objection under Article 83 EPC should be raised as long as the application discloses a plausible therapeutic concept and **there are no substantiated doubts** that the concept can be put into practice (T 578/06, Reasons 13; T 2015/20). Nevertheless, any such data or considerations have to be evaluated as to whether they support achievement of the therapeutic effect across the whole scope claimed.

For example, an observed reduction/inhibition of biomarkers (*in vitro* data) cannot be used as proof of a therapeutic activity **if the link to the successful treatment is not established in the application as filed**. Common general knowledge might fill in the gap and establish the link.

Importantly, if the application as filed does not demonstrate the product's suitability, **post-published data cannot remedy** that deficiency.

The following is an overview of the required level of data at the application's filing or priority date with the corresponding case law decisions:

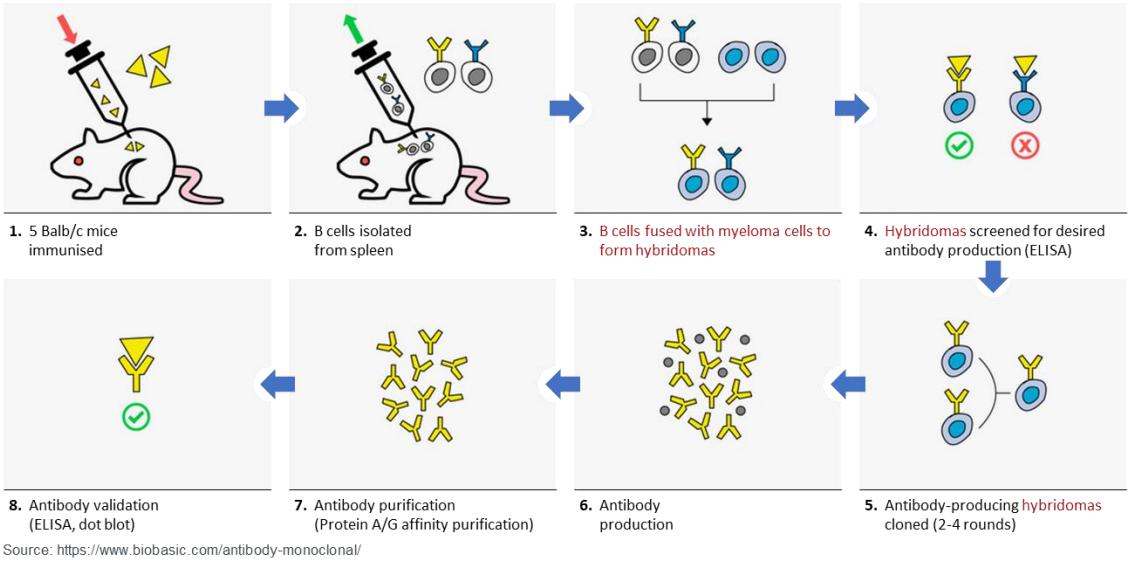


Legal references:
Art. 83 EPC, CL Book II.C.7.2

4. Level of disclosure required for antibodies

Antibodies can also be defined by the hybridoma. Hybridomas are hybrid cells produced by fusing an antibody-producing lymphocyte with a tumour cell and used to culture continuously a specific

monoclonal antibody (Encyclopedia of Toxicology, 3rd edition, 2014). The hybridoma is the main feature in the standard generation of monoclonal antibodies:



Source: https://www.biobasic.com/antibody-monoclonal/

Antibodies may be defined through a deposited hybridoma cell producing the antibodies.

In that case, the general requirements for deposited biological materials apply and the requirements of Rules 31-34 EPC must be satisfied.

Examples

Example 1: *"A monoclonal antibody binding to antigen X obtained from the hybridoma cell line 57DX79."*

- Hybridoma cell line 57DX79 not commercially or publicly available
- Cannot be reproducibly provided if defined by an internal designation name only
- Problem of sufficiency of disclosure (Article 83 EPC)

Example 2: *"A monoclonal antibody binding to antigen X obtained from the hybridoma cell line deposited at the ATCC on 22 May 1996 under Accession No. 111111."*

- Hybridoma deposited at a recognised international depositary institution under the Budapest Treaty (Rule 31 EPC) no later than the filing date of the application
- Requirements of Article 83 EPC fulfilled

Legal references:

Art. 83 EPC, R. 31 EPC, R. 32 EPC, R. 33 EPC, R. 34 EPC, GL G-II, 6.1.6

5. Post-published evidence

Post-published evidence can be used to show that the general conceptual disclosure of the invention when filed was indeed reproducible without undue burden at the relevant filing date.

Post-published evidence cannot remedy any insufficient disclosure existing at the time of filing due to a lack of guidance for performing a particular aspect of the invention.

Sufficiency of disclosure must be shown to exist at the patent's effective date. If the description of the patent specification provides no more than a vague indication of a possible medical use for a chemical compound yet to be identified, more detailed evidence cannot later be used to remedy the fundamental insufficiency of disclosure of that subject-matter.

Generally, post-published evidence can only be considered to back up positive findings in relation to the disclosure in a patent application.

Post-published evidence may only be considered to back up the findings in the application in relation to the use of the compound(s) as a pharmaceutical if the medical use was already plausible at the time of filing.

Examples

Example 1:

An application related to a method that was insufficiently disclosed. When a document was submitted five years after the priority date as evidence that the claimed method was in fact reproducible and did work, this evidence could not be accepted as the knowledge of this later document was not available at the relevant filing date (T 1329/11).

Example 2:

Claim 1 related to a subtilisin (a detergent enzyme) variant with mutations at one or more of positions 174, 176 and 193.

The application alleged that the mutation led to lower allergenicity compared with the prior-art enzyme.

The patent disclosed ***a method*** of finding *which mutations were relevant for reducing allergenicity*, which identified 32 positions of mutations that could be relevant for lowering allergenicity. The examples showed that some of these mutants had lower allergenicity; the patent did not exemplify mutations at positions 174, 176 and 193.

The patent assumed that any mutations for positions 167-176 and 193-197 would provide the effect of lower allergenicity.

This assumption lacked plausibility; the patent did not disclose that mutations at positions 174, 176 and 193 had lower allergenicity. Post-published evidence demonstrating lower allergenicity for mutations at positions 174, 176 and 193 was not accepted because there had been a lack of plausibility at the time of filing, which could not be remedied with post-filed evidence (T 861/08).

Legal references:
Art. 83 EPC; Art. 56 EPC, CL Book II.C.6.8, CL Book II.C.7.2

6. Sequence listing

Under the Guidelines for Examination, if the European patent application discloses nucleotide and amino acid sequences within the meaning of Rule 30(1) EPC, they are to be represented in a

sequence listing which conforms to WIPO Standard ST.26. The sequence listing must be filed in electronic form, i.e. in TXT format.

Why do we need sequence listings?

- Patentability/prior-art searches: standardised electronic format for homology/identity searches
- Public disclosure: electronic publication of sequences in appropriate databases (publicly accessible, standard format, searchable) makes them truly accessible to the public

Exceptions to the requirement to file a sequence listing (OJ EPO 2021, A96, A97; J 8/11):

- no actual sequences in the application
- sequences shorter than ten nucleotides or four amino acids
- application as originally filed identifies prior-art sequences by their database accession number and either the version number or the database release number

Compared to the previous WIPO standard, according to ST26 also peptides containing D-amino acids, nucleotide analogues and branched sequences require a sequence listing.

Examples

Examples where a biological sequence is considered an essential feature of the invention would be a diagnostic method using a particular nucleic acid sequence or a product made by a biochemical process using an enzyme with a particular amino acid sequence.

An example of ambiguous identification would be the citation of an accession number of a certain protein in the database of the European Molecular Biology Laboratory with no indication of which version number or database release number is meant when there are several such numbers referring to different sequences of the protein.

Legal references:

Art. 83 EPC, Rule 30 EPC, GL F-II 6; A-IV 5, OJ 2021 A96, A97, T 2477/12; J 8/11

7. Beyond the course

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

- Baker, Scott, and Claudio Mezzetti. "Disclosure as a Strategy in the Patent Race." *The Journal of Law & Economics*, vol. 48, no. 1, [The University of Chicago Press, The Booth School of Business, University of Chicago, The University of Chicago Law School], 2005, pp. 173–94, https://doi.org/10.1086/426879.

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