

Learning path for patent examiners

Assessment of inventive step: chemical inventions: Intermediate level

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Introduction

This publication, "Assessment of inventive step: 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.

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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:

- Assessing the capabilities of a person skilled in the art in area of biotechnology;
- Usefulness of post-filed data for establishing a technical effect in the context of proving an inventive step;
- Limitations on admissibility of post-filed data as proof apply;
- Post-filed data cannot cure a lack of plausibility as of filing.

2. The person skilled in the art in biotechnology

The skilled person is unique for each technical field, and the case law defines the skilled person in biotechnology in a number of decisions:

- T.455/91: a person skilled in the art was considered to be **conservative** and would never go against an established prejudice, try to enter unpredictable areas or take incalculable risks. The notional skilled person would transfer technology from a neighbouring field to their specific field of interest if doing so entailed routine experimental work involving only routine trials.
- T.60/89: a skilled person in genetic engineering in 1978 could not be deemed to be a Nobel prize winner, even if a number of scientists working in the field at that time had actually been awarded that prize. Rather, they should be assumed to be a scientist (or team of scientists) working as a teacher or researcher in the laboratories which made the transition from molecular genetics to genetic engineering at that time.
- T.500/91: the board ruled that the average skilled person – who might also be a team of specialists in the relevant field – **operated at a practical level**, and the technical development which might normally be expected of them did not include solving technical problems through scientific research.
- T.412/93: the patent related to the production of erythropoietin. The parties agreed that in this case the skilled person should be treated as a team of three, composed of one PhD researcher with several years' experience in the aspect of gene technology or biochemistry under consideration, assisted by two laboratory technicians fully acquainted with the known techniques relevant to that aspect. The composition of the team might vary depending on the knowledge and skills required by the particular aspect dealt with.

Legal references:

Art. 56 EPC, CL Book I.D.8.1.3

3. Post-filed data to establish a technical effect

The assessment of inventive step often hinges on the presence or absence of a technical effect.

While this is to be assessed **on the basis of the information in the patent** together with the common general knowledge available to the skilled person at the time the application is filed, it does not exclude the possibility of filing supplementary data during the examination phase to support an inventive-step argument.

It may be that during examination, in order to address the obviousness of the claimed subject-matter, supplementary data is filed to **prove the existence of a surprising technical effect**. This supplementary data may lead to a **reformulation** of the objective technical problem.

The supplementary data can be taken into account if the **reformulated problem to be solved has a basis in the application as filed**.

That problem may not have been mentioned **explicitly** in the application as filed. However, for the reformulation of the problem to be allowable, the technical effect must **at least be one implicitly** related to the problem the application claims to solve.

Furthermore, post-filed evidence in support of the fact that the claimed subject-matter does solve the problem can only be considered if it is **already credible from the disclosure in the patent that the problem is indeed solved**. In other words, supplementary post-published evidence may not serve as *the sole basis* to establish that the problem is solved.

Post-published evidence thus can be used only to back up the teaching derivable from the application – it cannot create any new teaching. New effects may only be taken into account if implied by or related to the technical problem initially suggested in the originally filed application.

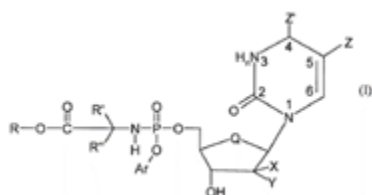
Occasionally, supplementary data is filed to prove that the objective technical problem was solved over the whole claimed scope.

The above-outlined practice for taking into account post-filed evidence in the assessment of inventive step has been confirmed in decision G 2/21 of the Enlarged Board of Appeal; the headnotes of this decision read as follows:

- I. Evidence submitted by a patent applicant or proprietor to prove a technical effect relied upon for acknowledgement of inventive step of the claimed subject-matter may not be disregarded solely on the ground that such 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.
- II. A patent applicant or proprietor may rely upon a technical effect for inventive step if the skilled person, having the common general knowledge in mind, and based on the application as originally filed, would derive said effect as being encompassed by the technical teaching and embodied by the same originally disclosed invention.

Examples

The application as filed related to:



Claim 1:

for use in treating disease X.

There were three examples in the application – [CPF-31](#), [CPF-41](#), [CPF-42](#) – which showed them being active in treating disease X.

The prior art disclosed compound **CPF2** for use in treating disease X.

The applicant provided supplementary post-filed data during examination to argue that the claimed compounds were better drugs than the prior-art compound CPF2. The following data was submitted to prove that the difference led to effects like improved renal clearance, better bioavailability and longer half-life:

compound	renal clearance	bioavailability	half-life
CPF2	0.4	0.6	5
CPF-31	0.3	0.8	10
CPF-40	0.3	0.9	10
CPF-41	0.2	0.6	12

Although the supplementary data was post-filed, it could be used because:

- a. it did not create any new teaching (still active against disease X)
- b. *even though the technical effects observed were not mentioned in the application as filed* (better renal clearance, better bioavailability, etc.) they addressed problems to solve that were always **implicit in the development of new pharmaceutical drugs**

Thus, improving medications is always an underlying problem in pharmaceutical applications, and it is possible to use any fundamental, medically relevant technical effect based on evidence that was filed after the filing date and demonstrates an improvement over the prior art.

Legal references:

Art. 56 EPC, GL G-VII, 5.2, GL G-VII, 11, T 184/82, T 386/89, CL Book I.D.4.6, G 2/21

4. Beyond the course

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

- Presentation by Eveline Lancon, Karin Marchand: "Post-filing of experimental data and the burden of proof", European Patent Academy, Examination Matters 2021; <https://e-courses.epo.org/course/view.php?id=250>.
- Presentation by Katell Le Flao, "Post-filed evidence – a risky game", European Patent Academy, Examination Matters 2018, <https://e-courses.epo.org/course/view.php?id=133>

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