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Learning path for patent examiners

Assessment of clarity: chemical inventions: Intermediate level

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Introduction

This publication, "Assessment of clarity: 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.

Contents

Legal references

1. Learning objectives

Participants to this course will learn:

- About factors that influence the clarity of chemical, pharmaceutical or biotech claims;
- Terms frequently leading to a lack of clarity in such claims are discussed;
- Typical examples of relative terms, ambiguous wording, functionally defined features and result-to-be-achieved features are presented;
- Parametric claims, functionally defined diseases or functionally defined family of compounds are a source of clarity objections;
- A lack of clarity due to unclear or ambiguous terms may trigger insufficient disclosure and lack of inventive step.
- How to correctly apply "comprising" and "consisting"

2. Relative terms such as "approximately", "about", "substantially"

Claims using relative terms will be objected to under Article 84 EPC because they do not make it possible to clearly establish the scope of the claim.

Where terms such as "about" or "approximately" are applied to a particular value (e.g. "about 200°C" or "approximately 200°C"), the value will be interpreted as "200°C +/- the error margin of the measurement method".

Examples of relative terms are "about", "approximately", "substantially", "thin", "thick" and "heavy".

Relative or similar terms such as "thin", "wide" or "strong" constitute a potentially unclear element as their meaning may change depending on the context. For these terms to be allowed, their meaning must be clear in the context of the whole disclosure of the application or patent.

If the applicant uses a relative or similar term as the only feature to distinguish the subject-matter of a claim from the prior art, the use of this term is objected to under Article 84 EPC unless the term has a well-established meaning in the particular art.

When the use of a relative term is allowed in a claim, the division will interpret the term in the least restrictive way possible when determining the scope of the subject-matter of the claim. Consequently, in many cases, a relative term is not limiting for the scope of the subject-matter of a claim.

Some of the above-listed "relative terms" have a clear, well-recognised meaning in a particular technical context, e.g. "**thin**-layer chromatography", "**heavy** metal" or "**high**-frequency transmitter".

Examples

A claim using the expression "a thin metal plate" as a differentiating feature cannot be held novel over prior art disclosing the same matter with the feature "metal plate".

Whether a metal plate is "thin" or not only becomes apparent in comparison with another one; it does not define an objective and measurable thickness. For instance, a metal plate three millimetres thick is thin when compared with a plate five millimetres thick but thick when compared with a plate one millimetre thick.

A claim characterises a chemical substance by XRPD data.

"Crystalline form A of drug X, characterised by 2-theta main peaks in the XRPD at about 9.0, 14.2, 23.9 and 27.1."

The claim is not clear due to the relative expression "about". A skilled person understands that the experimentally obtained value is subject to a certain degree of variation. Instead, it would have been more accurate to report the value with the margin of error/degree of uncertainty: e.g. 27.1 +/- 0.2° 2-theta, etc.

Legal references:
Art. 84 EPC, GL F-IV, 4.6.2, CL Book II.A.3.6

3. "Comprising" versus "consisting of"

A claim directed to an apparatus/method/product "**comprising**" certain features is construed as including the stated features but not to the exclusion of other features.

On the other hand, if the wording "**consisting of**" is used, then **the only features** present in the apparatus/method/product are those following said wording.

The general meaning of the verb "***to contain***" is "to have in it", "to hold", "to include", "to encompass", so it is considered equivalent to "comprising" (T 56/08).

If a claim for a chemical composition refers to the fact that it "**consists of** components A, B and C" by their proportions expressed in percentages, the presence of **any additional component is excluded** and therefore the percentages must add up to 100% (see T 711/90).

Examples

A composition *"consisting of A, B and C*" only has three components. If the quantities of the three components are defined by ranges, the sum of two maxima and one minimum must add up to 100%.

Thus, the following claim is not clear since, even when % A and % B are at their maximum (i.e. 40% + 40%), the sum with the lower limit (10%) does not add up to 100%.

Claim 1: Cosmetic composition consisting of:
15 - 40 % A
20 - 40 % B
10 - 60 % C

Legal references:
Art. 84 EPC, GL F-IV, 4.20, CL Book II.E.1.15, T 759/10, T 711/90, T 56/08

4. Dosage forms characterised by a result to be achieved

Results to be achieved must be clearly identified and analysed and should not be confused with functionally defined features. A result to be achieved can lead to many different objections (even unity of invention; Article 82 EPC). However, most often the objections are made under Articles 84, 83, 54 and/or 56 EPC.

In view of Article 84 EPC, a result to be achieved may be allowed if the invention either can only be defined in those terms or cannot otherwise be defined more precisely without unduly restricting the scope of the claims, and if the result is one which can be directly and positively verified by tests or procedures adequately specified in the description or known to the person skilled in the art and which do not require undue experimentation (see T 68/85).

For example, the invention may relate to an ashtray in which a smouldering cigarette end will be automatically extinguished due to the shape and relative dimensions of the ashtray. The ashtray may vary considerably in a manner that is difficult to define while still providing the desired effect. As long as the claim specifies the construction and shape of the ashtray as clearly as possible, it may define the relative dimensions by reference to the result to be achieved, provided that the specification includes adequate directions to enable the skilled person to determine the required dimensions by routine test procedures (see Guidelines F-III, 1-3).

Careful analysis is necessary: what is actually described as the result to be achieved?

Example claim: "Tablet which has a geometric shape and size that is suitable to be swallowed by a human patient."

In this case, the tablet cannot otherwise be defined more precisely without unduly restricting the scope of the claims and does not require undue experimentation (Guidelines F-IV, 4.10). No objection is therefore necessary.

It is important that the claims define the features that are essential for the invention to work, or they must be able to be established without undue burden (Articles 83 and 84 EPC).

If the claimed invention lacks reproducibility, this may become relevant under the requirements of sufficiency of disclosure or inventive step (Articles 83 or 56; Guidelines F-III, 12). The technical effect achieved by the invention solves the problem on which the application is based. 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 must be objected to under Article 83 EPC. Otherwise, i.e. if the effect is not expressed in the claim but is part of the problem to be solved, there is an inventive-step issue.

Example claim: "Tablet comprising ibuprofen, 50-60 wt.% PVP as binder and 20-30 wt.% hydroxypropyl starch, which remains stable for at least five years at 21°C and relative humidity from 40-60 vol.%."

In this case, the examples show that what is achieved by PVP and HP starch according to the claim is stability. No objection is therefore necessary.

Claim: "Tablet comprising ibuprofen, which remains stable for at least five years at 21°C and relative humidity from 40-60 vol.%."

In this case, the examples show that stability is what is achieved but the claim does **not disclose any features that lead to this effect**. Objections under Articles 83 and 84 EPC, or even Articles 54 and 56 EPC, are therefore possible.

Results to be achieved are different from **functionally defined features**, which form part of the common general knowledge and do not need to be objected to (e.g. "table-board with supporting means").

Example claim: "Tablet comprising ibuprofen with an enteric-release coating."

In this case, the skilled person knows these kinds of coatings as they are disclosed in standard literature (**common general knowledge**) and are commercially available (e.g. Eudragit); this is a **functionally defined feature**.

Claim: "Tablet comprising ibuprofen, a binding agent and a disintegrant."

Many excipients are often disclosed by their function; this is common general knowledge and indicates the presence of a **functionally defined feature.**

Legal references:
Art. 84 EPC, Art. 83 EPC, GL F-IV, 4.10, GL F-III, 12

5. Functionally defined families of compounds

In the biotechnology and pharmaceuticals fields in particular, compounds are often defined by their function rather than by their chemical structure ("reach-through claims"; Guidelines F-III, 9).

Under Article 83 and Rule 42(1)(c) EPC, the claim must contain sufficient technical disclosure of the solution to the problem.

A functional definition of a chemical compound ("reach-through" claim) covers all compounds with the activity or effect specified in the claim. It would be an undue burden to isolate and characterise all potential compounds (e.g. agonists/antagonists) without any effective pointer to their identity (see Guidelines F-III, 1), or to test every known compound and every conceivable future compound for this activity to see if it falls within the scope of the claim.

In effect, with a "reach-through" claim, the applicant is attempting to patent what has not yet been invented, and the fact that the applicant can test for the effect used to define the compounds does not necessarily confer sufficiency on the claim. In fact, it constitutes an invitation for the skilled person to undertake a research programme (Article 83 EPC). The allowability of the claim depends on whether **all** the following conditions are met:

- The specific compounds fulfilling the function are part of the common general knowledge, known, for example, from readily available prior-art documents or disclosed in the application in a plausible manner.
- The function can be verified by tests or procedures adequately specified in the description or known to the skilled person and which do not require undue experimentation.
- The entire content of the patent application unambiguously shows **that the function** (as opposed, for example, to the chemical structure, crystal structure, etc.) is **causal** for the solution of the problem addressed by the invention. In other words, it has to be reasonably clear that it is

possible to use not only the examples in the application but also any other compounds with the stated function, and what these compounds might be.

If all of conditions (i)-(iii) are fulfilled, the requirements of Articles 83 and 84 EPC are clearly met.

To assess whether the above criteria are met for the terms "agonist"/"antagonist" (by way of example), it first has to be determined whether the term antagonist/agonist in the context of the invention at issue is to be deemed directed to **a single target** or to a **pathway** possibly including multiple targets which may even be specifically defined in the application. In the latter case, it has to be clear which further targets are addressed by the agonists/antagonists as claimed. In other words, the targeted biological pathway has to be either disclosed in the application or known from the prior art.

Legal references:
Art. 84 EPC, Art. 83 EPC, GL F-III, 9

6. Functionally defined diseases

A medical use may relate to a disease defined by its name (e.g. cancer) or to the treatment of a symptom of a disease (e.g. pain). Functional definitions of a pathological condition, e.g. by a disease mechanism, are also allowable.

However, pursuant to Guidelines F-IV, 4.21, the claim can be deemed clear only if instructions, in the form of **experimental tests or testable criteria**, are available from the patent documents or from the common general knowledge and allow the skilled person **to recognise which conditions fall within the functional definition** and accordingly within the scope of the claim. It has to be self-evident that the functional definition actually relates to a disease and not a physiological state that does not necessarily correspond to a disease.

Moreover, where a functional limitation is used to limit a disease, care has to be taken as to whether this functional limitation in the context of the medical use defines a subtype of the disease or a new clinical situation that confers novelty, or whether this functional limitation **merely defines the mode of action of the compound** whose medical use is claimed for treating the disease/condition at issue. The latter situation does not establish novelty over a medical use of said compound for treating said disease/condition as such.

Moreover, functional definitions may be used wholly (T 1127/05) or partially T 1634/06) to define the disease to be treated and **can be used where a therapeutic effect can reasonably extend beyond the particular disease(s)** tested to encompass further diseases involving the same mechanism.

If the term "condition" is used in a functional definition, care has to be taken to check whether the claimed medical use is limited to a therapeutic application and does not also include non-therapeutic applications.

To make a technical contribution to the art and be considered an invention eligible for patent protection, the discovery of a new mechanism of action, even if it represents an important piece of scientific knowledge, still needs to find **a practical application in the form of a defined, real treatment of a pathological condition**. A new mechanism of action is only relevant with respect to

the novelty of a claim directed to a second medical use of a known compound or composition in so far as this mode of action **results in a new therapeutic use of the known product** (T 254/93, T 892/94, T 241/95, T 1048/98, T 486/01). This new therapeutic use is the technical feature which must be included in the wording of the relevant claims.

Examples:

- Compound X for use in treating a disease susceptible of being improved or prevented by selective occupation of the Z-receptor.

  The claim is a second medical use claim. The portion of the claim "a disease susceptible of being improved or prevented by selective occupation of the Z-receptor" is a functional definition of a disease that can be treated by compound X. The functional term thus represents a list of diseases.

  Whether the claim is clear depends on the situation and the prior-art knowledge around the "Z-receptor". It must be clear which diseases are meant by the functional definition and how to identify any further disease that might fall under the functional definition.

- Compound X for use in treating a disease characterised by a specific mutation of gene Y.

  If the mutation is shown to be causative for a specific disease, it can be accepted that the skilled person is able to identify further diseases on the basis of the identification of that mutation. If this is the case, the claim is clear and sufficiently disclosed.

- Compound X for use in treating a condition with increased expression of gene Y.

  The increase of gene Y may also cover a physiological variation of said expression of gene Y, which does not represent a disease. Thus, this claim also encompasses non-therapeutic applications. As to the therapeutic subject-matter, the disease is not defined. The gene expression is not a mechanism of action that clearly defines a pathological condition, so the claim is unclear.

  The claim also uses the term "condition", but the more appropriate wording would be: "Compound X for use in treating disease Z, in which the expression of gene Y is increased."

  In this case, the disease is defined and is further functionally limited by a gene expression signature. This does not define a mode of action but rather represents a limitation to a subtype of disease Y, so the claim is clear.

Legal references:
Art. 84 EPC, Art. 83 EPC, GL F-IV, 4.21, T 241/95, CL Book II.A.3.4

7. Ambiguous wording in chemistry

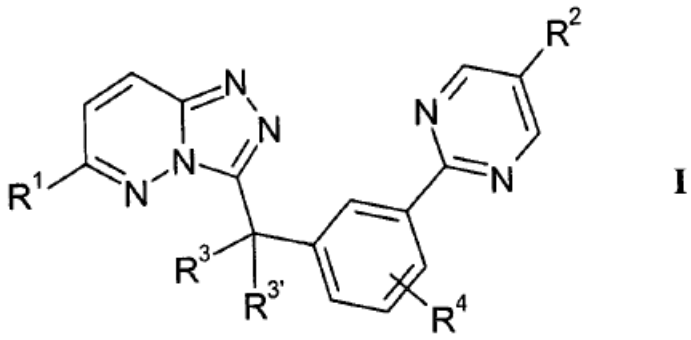
The end of compound claims often specifies conditions that extend the scope of the claims to "*derivatives*", "*analogues*", "*prodrugs*", "*metabolites*" and the like.

This renders the compound claims unclear – these terms expand the scope in an unclear manner (Article 84 EPC) as the degree of derivatisation, metabolisation, analogue formation, etc. is unclear.

There is no clear definition or common understanding of the extent of derivatisation, metabolisation etc., so the person skilled in the art cannot decide clearly which compounds are covered by the claims and which are not.

Examples

Claim 1 relates to Markush formula (I)



I

as well as to its *isomers, prodrugs, metabolites, esters and pharmaceutically acceptable derivatives*.

It is unclear if the scope ultimately extends even to small fragments of the structure resulting from metabolisation.

Legal references:
Art. 84 EPC, T 1054/06, T 279/07, T 1898/06 (derivatives)

8. Criteria for parameters in claims

The physical structure of products in claims may be characterised by specific parameters, provided that those parameters can be ***clearly and reliably determined*** by objective procedures which are usual in the art. Parameters may be permissible if:

a. The claims themselves are clear when read by the skilled person (not including knowledge derived from the description).
b. The method for measuring a parameter (or at least a reference to it) appears in its entirety in the claim itself.
c. The applicant ensures that the skilled person can easily and unambiguously verify if they are working inside or outside the scope of the claim.

The second criterion may also be considered fulfilled if the measurement method is within the skilled person's common general knowledge (because there is only one to use) or if there are several measurement methods available that all yield the same result within the bounds of measurement accuracy.

The method for determining the parameter should be able to produce consistent values so that the skilled person carrying out the invention will know if they are working inside or outside the scope. If

the parameter is so ill defined that this is not possible, meaning that the technical measurement results in an undue burden, the parameter in the claim will lead to a clarity or insufficiency objection.

There is a delicate balance to strike between clarity and sufficiency with unclear parameters.

Examples

A claim relates to:

"A tissue product ... with tensile strength between 8.4 and 41.9 N/m per g/m^2, ..."

There are several methods for measuring tensile strength, but different measurement methods produce different values. Neither the claim nor the description specified the method used to measure the tensile strength.

The fact that there were several well-established methods for measuring this parameter meant that while the skilled person was able to measure a value, they were unable to discern if they were working inside or outside the scope of the claim, particularly with values obtained around the endpoints of the claimed range.

The claim was therefore sufficiently disclosed but unclear.

Legal references:

Art. 84 EPC, GL F-IV, 4.11, GL F-III, 11, GL F-IV, 6.4, CL Book II.C.5.5, T 849/11, T 1414/08

9. Beyond the course

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

- Andrew F. Christie, "Reach-through Patent Claims in Biotechnology: An Analysis of the Examination Practices of the United States, European and Japanese Patent Offices", ISSN 1447-2317, ResearchGate 2006, https://www.researchgate.net/publication/228191907
- Presentation Tim Lange, "Pitfalls in Chemistry and how to avoid them", European Patent Academy, Examination Matters 2012
- Presentation Roberto Menchaca, "Assessment of sufficiency of disclosure in claims containing parameters", European Patent Academy, Examination Matters 2019, https://e-courses.epo.org/course/view.php?id=133

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