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Assessment of novelty: chemical inventions: Entry level

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Introduction

This publication, "Assessment of novelty: chemical inventions, Entry 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:

- The principle of novelty assessment for Markush formulae
- The definition and the legal basis of a "Kit of parts"
- The assessment of a combination of active ingredients in a claim in view of Art. 123(2), 54 and 56 EPC
- An introduction to the definition of a medicament under the EPC and the purpose limiting value and legal basis for medical use claims
- The specific considerations applying to contraceptive agents

2. Novelty of Markush formulae

A Markush structure is a representation of a chemical structure used to indicate a group of related chemical compounds that share a "single structural similarity" (typically the core to which the different variables are attached).

They are commonly used in chemistry texts and in patent claims. Markush structures are depicted with multiple independently variable groups, such as R groups, in which a side chain can have a different structure. It is a concise way of claiming a structural chemical space as opposed to depicting lists of molecules and detailing every atom combination in the molecule.

Applicants often deliberately choose Markush formulae to "hide" the most promising structure falling within the structural space by "diluting" the most promising candidate structure with other less interesting analogues.

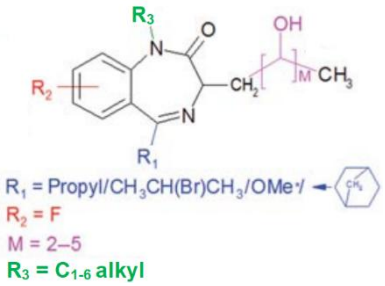
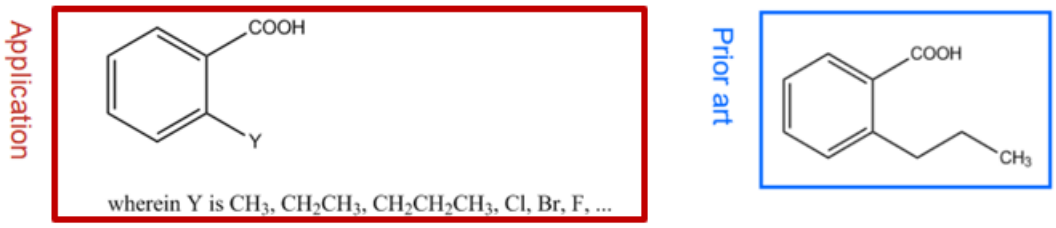


Figure 1: example of a Markush formula

A discrete, disclosed compound falling under the scope of a claimed Markush formula takes away the novelty of the claim to that Markush formula.



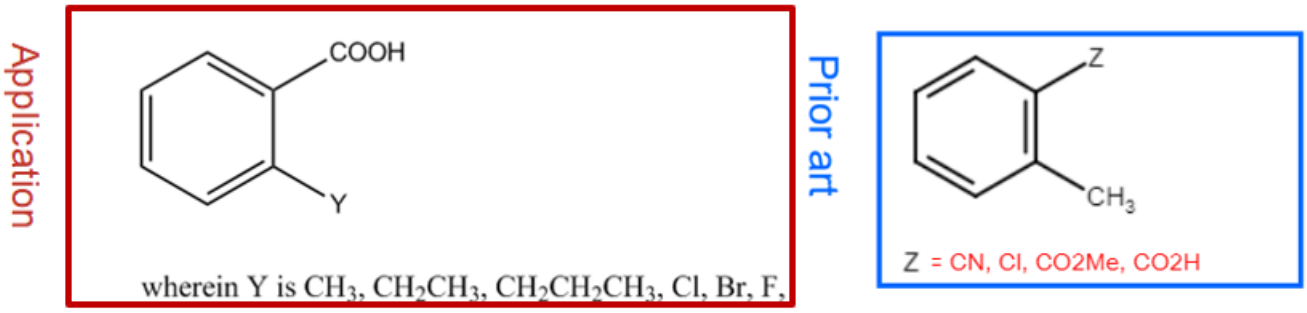
Example: the blue, prior-art compound falls under the scope of the generic Markush formula and takes away the novelty of the application.

Typically, to assess the novelty of a Markush formula, only actual compounds that fall under the scope of the Markush formula are relevant. In general, a prior-art Markush formula that overlaps with another claimed formula is not novelty-destroying as long as there are no concrete examples in the disclosed area of overlap.

Typically, the area of overlap without any disclosed compounds is not novelty-destroying because any specific chemical compound defined by the prior-art Markush formula would be the result of a selection from multiple lists. When claimed and prior-art Markush formulae overlap, what counts are the concrete molecules disclosed in the area of overlap.

Potentially, a compound that is otherwise undisclosed but covered under a prior-art Markush formula can still be novelty-destroying owing to the principle of "selection from one list".

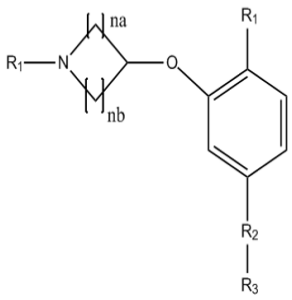
This is illustrated below:



Consider that the only concrete example disclosed by a prior-art Markush formula (in the blue box) is the **methy**l-o-Me-benzo**ate**. This compound does not take away the novelty of the claimed Markush formula (in the red box). However, the novelty-destroying o-Me-benz**oic acid** is considered explicitly disclosed as the result of a selection from a single list – choosing only Z = -CO2H leads to a compound falling under the Markush formula in the red box.

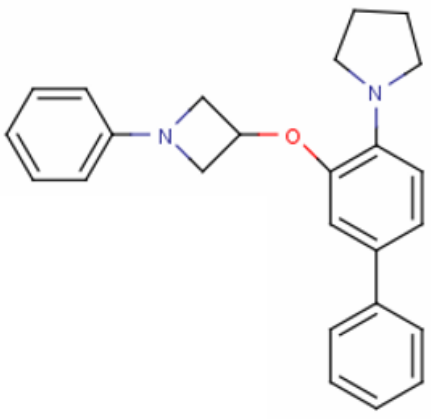
Examples

A Markush formula claim specifies that:



R^1 is phenyl, heterocyclyl ... optionally substituted with one to five F;
R^2 is bond, $-SO_2NR^5-$, -OC(O)-, -C(H)=N-O- or -C(O)NH-;
R^3 is aryl;
n_a and n_b are each an integer ranging from 0 to 6;

The prior art discloses this compound:



The Markush formula is not novel because the prior-art compound falls under the scope of the formula (when, in the above formula, R^1 = phenyl and pyrrolidinyl as a particular form of "heterocyclyl", R^2 = bond, R^3 = phenyl as a particular form of "aryl", and n_a and n_b are both 1).

Legal references:
Art. 54 EPC, GL G-VI, 7, CL Book II.E.1.6.2

3. Kits-of-parts

The boards of appeal describe a "kit-of-parts" as the juxtaposition of separate but functionally interacting individual components.

If there is a prior-art document that discloses the same ingredients (or combination of ingredients) but does not disclose the instructions, the current practice in biotech and pharma is to object to a claim directed to a kit with instructions under novelty.

The instructions in the claim are regarded as merely a presentation of information, with no technical effect on the claimed product.

("Technical novelty", T 0553/02, T 1020/03 and T 2016/11)

Examples

Claim 1: A method for diagnosing disease X comprising measuring marker Y by adding reagent A and reagent B to a sample leading to a change in colour which indicates disease X.

Claim 2: A kit (for carrying out the method) comprising reagents A and B and instructions for carrying out the method of claim 1.

Legal references:
Art. 54 EPC, CL Book I.C.7.1.3, T 553/02, T 1020/03, T 2016/11

4. Combination of active ingredients

A claim may be limited by including additional features provided the resulting combination **was directly and unambiguously disclosed** in the application as originally filed either explicitly or implicitly (see Guidelines H-IV, 2.1) and does not relate to an invention which was not searched (see H-II, 6 and H-II, 7.2).

If the resulting combination is novel over the application as originally filed (see the test for novelty given in Guidelines G-VI, 2), the amended claim does not fulfil the requirements of Article 123(2) EPC.

The fact that the resulting combination can be deemed "not inconsistent" with the description (T 495/06), "reasonably plausible" (T 824/06) or "obvious" in view of the application (T 329/99) is not sufficient for an amendment to be allowable under Article 123(2) EPC since it has to be directly and unambiguously disclosed.

A claim may be limited by including additional features, for example: (a) from dependent claims which were dependent on the claim to be limited; (b) from the description (see also H-V, 3.2.1); (c) from drawings (see H-V, 6); (d) arising from the conversion of an independent claim to a dependent claim; provided the above requirements are fulfilled.

The **two-list principle** applies **as a novelty test**, for example:

a. Selection from sub-lists considered to be a selection from a single list (Article 123(2) EPC fulfilled)
   - List 1 (active groups): opioids, **NSAIDs**, anti-cancer agents, etc.
   - List 2 (active ingredients within a single group in List 1): ASS, diclofenac, **ibuprofen**

b. Twofold selection from a single list = twofold selection from two identical lists (Article 123(2) EPC not fulfilled)
   - List 1: ASS, …, **diclofenac**, ibuprofen, …, **naproxen**, celecoxib, etc.

If the **combination of active ingredients yields a synergistic effect**, any such synergism is considered to be unforeseeable in relation to the **inventive-step assessment**. In T 1814/11, the problem to be solved was to provide an alternative synergistically active fungicidal composition based on prothioconazole.The board concluded that synergistic effects were not foreseeable. In other words, even if a combination of two specific compositions had a synergistic effect as in document 1, this synergy could not necessarily be expected if the structure of one of the two compositions were modified. As a rule, synergy was not foreseeable and therefore could not be attributed to a specific mechanism of action and/or structure. The board dismissed the respondent's suggestion that the possibility of trial-and-error experimentation could lead to a finding of obviousness.

Legal references:
Art. 123(2) EPC, Art. 54 EPC, Art. 56 EPC, GL H-V, 3.2, CL Book II.E.1.6.2, T 1221/07, T 1374/07, T 1814/11

5. Medicaments

Purpose-limited product claims under Article 54(4) and (5) EPC are limited to a **substance or composition** in the context of its medical use which confers novelty and non-obviousness, if any, on the claimed product. Accordingly, **a device is not intended** to enjoy the purpose limitations under Article 54(4) and (5) EPC.

Although neither the European Patent Convention nor the Guidelines for Examination give an explicit definition of substance, composition or medical devices, the Guidelines (G-VI, 6.1.1) do refer to T 1758/15 for further guidance on products that can be deemed "substances or compositions" as per Article 54(4) and (5) EPC. Generally, a product qualifies as a "substance or composition" under Article 54(4) and (5) EPC if it is the active agent or ingredient in the specific medical use and if the therapeutic effect can be ascribed to its **chemical properties** (see G 5/83 and T 1758/15).

For example, consider a filler material which is injected between a first tissue targeted for radiation treatment and a second sensitive tissue which is to be protected from radiation. If the shielding effect of the filler material is achieved **by a mere mechanical displacement** of the sensitive tissue relative to the target tissue, due to the volume it occupies between the two tissues, the filler material **qualifies as a device** rather than a substance or composition. On the other hand, if the filler material provides a radiation-reducing effect for the sensitive tissue that could be **attributed to its chemical properties**, it would be considered a **"substance or composition"** as per Article 54(5) EPC.

Furthermore, purpose-limited product claims under Article 54(4) and (5) EPC are limited to "methods referred to in Article 53(c) EPC", specifically to methods for treatment of the human or animal body by surgery or therapy and *in vivo* diagnostic methods practised on the human or animal body.

The concept of therapy is any treatment designed to cure, alleviate, remove or lessen the symptoms of a disorder or malfunction of the human or animal body:

- **curative** therapy, such as healing or curing of diseases, illnesses, malfunctions, disorders, injuries (T 19/86)
- **symptomatic** therapy of a disease or relief of pain, discomfort or incapacity, even if of natural origin, e.g. due to menstruation or pregnancy (T 81/84, T 24/91, T 443/01)

- **prophylactic** therapy, such as vaccination (T 19/86), immunostimulation (T 780/89), removal of plaque (T 290/86)

It is clear from T 1758/15 that "substance or composition" is not restricted to medicaments. It is also generally accepted that cells, diagnostic agents and prophylactics can benefit from Article 54(4) and (5) EPC, as can kits, scaffolds and matrices comprising these substances or compositions.

Legal references:
Art. 53(c) EPC, Art. 54(4) EPC, Art. 54(5) EPC, CL Book I.B.4.5.1, CL Book I.C.7.2.4 g

6. Limiting value of the "for use" expression in medical use claims

Section F-IV, 4.13.1 of the Guidelines states: "… a claim to a substance or composition for a particular use is construed as meaning a substance or composition which is in fact **suitable for the stated use**; a known product which *prima facie* is the same as the substance or composition defined in the claim, but which is in a form which renders it unsuitable for the stated use, does not deprive the claim of novelty. However, if the known product is in a form in which it is in fact suitable for the stated use, though it has never been described for that use, it deprives the claim of novelty."

Under **Article 53(c) EPC**, claims directed to methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body are excluded from patentability. This provision "**shall not apply to products, in particular substances or compositions, for use in any of these methods"**.

The medical use claim format is thus an **exclusive sub-category** of an entity or product claim, i.e. a "purpose-limited entity claim". It is deemed "exclusive" because it is only for methods/uses **that are excepted from patentability under Article 53(c) EPC**.

Article 54(4) EPC reads: "Paragraphs 2 and 3 shall not exclude the patentability of any substance or composition, comprised in the state of the art, for use in a method referred to in Article 53(c), provided that its use for any such method is not comprised in the state of the art."

Examples

- Cup for drinking coffee = cup for drinking tea ("suitable for")
- Mould for molten steel ≠ plastic mould for ice cubes ("not suitable for")
- Composition comprising substance X **for use** in medicine = novel over a composition comprising substance X for (or even "for use in") coating ships

Legal references:
Art. 53(c) EPC, Art. 54(4) EPC, Art. 54(5) EPC, GL F-IV, 4.13.1

7. First medical use – legal basis

Under Article 53(c) EPC, methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body ("medical methods") are excluded from patentability. This is to ensure that doctors can cure a human or animal without being constrained by patent restrictions.

However, this provision **does not apply to products**, in particular substances or compositions, for use in any of these methods.

Accordingly, a claim in the method or use category cannot be protected, but a product limited to that purpose can (purpose-limited product claim).

Under Article 54(4) EPC, the general rules of law relating to novelty do "not exclude the patentability of any substance or composition, comprised in the state of the art, **for use** in a method referred to in Article 53(c) EPC, provided that its use for any method [referred to in that paragraph] is not comprised in the state of the art".

Thus, in addition to the general concept of novelty, this article introduces **a special concept of novelty unknown in other technical fields** in respect of substances and compounds used in surgical and therapeutic treatment and in diagnostic processes carried out on humans and animals. Its purpose is for granting a patent to anyone who has made the unexpected discovery that a known substance has therapeutic value. Article 54(4) EPC applies to the assessment of novelty only – the remaining requirements of the EPC, such as inventive step, of course still need to be met independently of Article 54(4) EPC.

According to the case law of the boards of appeal, whoever is the first to disclose a substance or composition for use in a medical method should receive broad protection covering any use in a medical method, even if the application only discloses one specific use (such as treating asthma). In this case, a broad claim relating to "Substance x for use in medicine/therapy" is acceptable.

Examples of claims that are **NOT** medical use claims:
- substance/composition X for use in a cosmetic method, etc.
- substance/composition X for use in an *in vitro* method, etc.

because:
- cosmetic/*in vitro* methods not subject to Article 53(c) EPC
- so Article 54(4) and (5) EPC not applicable

Therefore, novelty is destroyed by any substance/composition that is suitable for this method, even if it were disclosed for a different intended purpose, e.g. for use as a nutrient.

Examples

A claim "Substance X for use in medicine/therapy/treatment of a subject"

and a claim "Substance X for use in treating asthma"

are both novel over a prior-art document disclosing substance X for (or "for use in" or "used for") diesel engine combustion acceleration.

Legal references:
Art. 54(4) EPC, GL G-VI, 6.1, CL Book I.C.7.1

8. Second or further medical use – legal basis

Article 54(5) EPC allows further patent protection for known substances or compositions for specific use in a method referred to in Article 53(c) EPC, provided that this specific use is not known from the state of the art.

Like with the first medical use under Article 54(4) EPC, the scope of protection of purpose-limited claims under Article 54(5) EPC is limited to the substance or composition in the context of its medical use, which confers novelty and non-obviousness, if any, on the claimed product. This principle applies to substances and compositions only and cannot be extended to other products.

In the early 1980s, the Enlarged Board of Appeal was asked to decide whether any further medical use could receive patent protection under the EPC in spite of the wording of Article 54(5) EPC 1973, corresponding to today's Article 54(4) EPC, which seemed to limit patentability to the first medical use.

The Enlarged Board extended the notional novelty provided for in today's Article 54(4) EPC to each further medical use defined in a "Swiss-type claim", i.e. in a claim "directed to the use of a substance or composition for the manufacture of a medicament for a specified new and inventive therapeutic application" (G 5/83). With the EPC 2000 revision, a new Article 54(5) EPC was introduced to provide protection for second medical uses. For medical uses covered by this new Article 54(5) EPC, "Swiss-type claims" are not accepted as "purpose-limited entity claims" anymore.

The new Article 54(5) EPC eliminates any legal uncertainty regarding the patentability of further medical uses. It unambiguously permits purpose-related product protection for each further new medical use of a substance or composition already known as a medicine.

A good example of this kind of second medical use being a scientific discovery is Aspirin, which has long been established as a useful analgesic and antipyretic. In the 20th century, scientists discovered many details of Aspirin's anti-inflammatory and analgesic properties, including its molecular mechanism of action. In addition, the latter half of the century brought reports that daily, low doses of Aspirin could prevent myocardial infarction and stroke, due to the inhibition of thrombocyte aggregation. If a second (or further) medical use of this kind is unexpected, should it not be patentable?

Examples

A claim "Substance X for use in treating asthma" is novel over a prior-art document disclosing substance X for use in treating cancer.

Legal references:
Art. 54(5) EPC, GL G-VI, 6.1, CL Book I.C.7.2

9. Contraceptive agents

The purpose limitation for contraceptive agents is not possible under Article 54(4) and (5) EPC because pregnancy is not a disease.

For example:

A claim "Product X for use in a method of contraception" would not be considered novel over the disclosure of product X per se because pregnancy is not a disease. Claims such as this can usually be reformulated as a method of contraception using product X.

Methods of contraception are generally patentable apart from the following exceptional situations:

1. The contraception has a **concomitant therapeutic effect** (Article 53(c) EPC) which is inevitably and inextricably linked to the contraceptive use, even where the concomitant therapeutic effect is not specifically claimed. In T 1635/09, the board did not allow a disclaimer to "non-therapeutic" with the contraceptive use as it did not change the situation, i.e. the method as such still involved therapy (Article 84 EPC).
2. The method involves applying a topical composition to the cervix. A board of appeal found that this was **not industrially applicable** under Article 57 EPC as it involved use in the "personal and private sphere" (T 74/93).
3. Implanting certain contraceptive devices such as the intra-uterine device may require a **surgical step** and is to be excluded from patentability for this reason under Article 53(c) EPC.
4. Contraception that has **reduced side effects** always involves therapy, even where only contraception is claimed (T 820/92).

Legal references:
Art. 54(4) EPC, Art. 54(5) EPC, Art. 57 EPC, GL G-VI, 6.1.2, CL Book I.B.4.4.1 b), I.E.1.2.1, T 74/93, T 1635/09, T 820/92

10. Beyond the course

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

- Jaenichen HR., Meier J., Hölder N. (2009) Medical Use Claims: EPC 2000 and its Impact on Prosecution and Enforcement. In: Pyrmont W.P..W.., Adelman M.J., Brauneis R., Drexl J., Nack R. (eds) Patents and Technological Progress in a Globalized World. MPI Studies on Intellectual Property, Competition and Tax Law, vol 6. Springer, Berlin, Heidelberg. https://doi.org/10.1007/978-3-540-88743-0_19

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