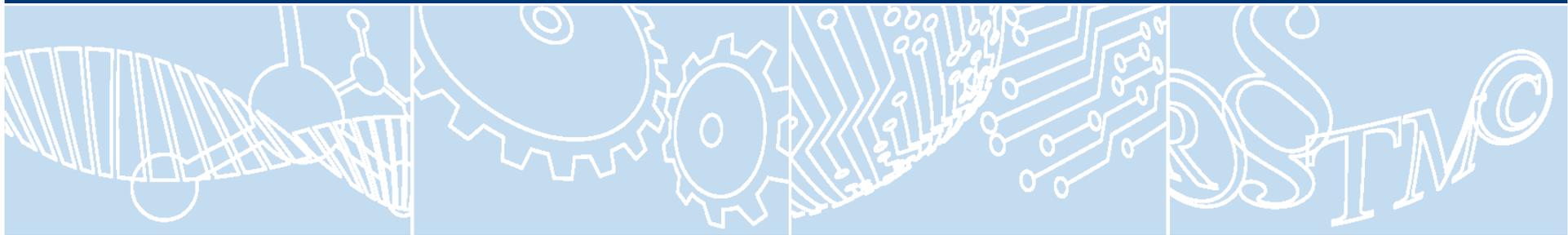


Recent experiences with Art. 123(2) EPC –
The ban on adding subject-matter not disclosed in the application as filed:
An oftentimes neglected provision when drafting patent applications

Dr. Joachim Renken



Contents

- a) Added matter and commercially important patents
- b) Basic legal principles
- c) The 123(2)/(3) trap
- d) Amendments without support I: non-essential features
- e) The fictitious skilled person vs. Real life appeal boards
- f) Intermediate generalizations
- g) Relying on claims
- h) Relying on examples
- i) Relying on drawings
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- l) Markush formulae

Contents

- m) Amendments without support II: Disclaimers
- n) Corrections
- o) Additional limitations of pre-grant amendments
- p) Amendments after grant

Introduction

- Claims may not comply with the EPC
 - Novelty
 - Inventive Step
 - Clarity
 - Support
 - Sufficiency of disclosure
- Claim amendment may be necessary
- Aim: Overcome objections with minimal loss of scope

Amendments are checked by the Examiner.
So where is the problem?

Pfizer's EP 702 555 B1 (Sildenafil) :

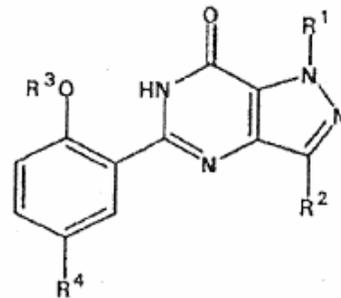
- ◆ Pfizer's applications contained two types of teaching:
 - (1): the use of compounds of a defined general formula; and
 - (2): the use of compounds defined only by their function of enzyme inhibition without a general formula.

Added Matter and Commercially Important Patents

Pfizer's EP 702 555 B1 (Sildenafil):

➤ Claim 1:

"The use of a compound of formula (I) ... or a pharmaceutically acceptable salt thereof ... for the manufacture of a medicament for the curative or prophylactic oral treatment of erectile dysfunction in a male animal, including man."



Pfizer's EP 702 555 B1 (Sildenafil):

➤ Claim 10:

"The use of a cGMP PDE inhibitor, or a pharmaceutically acceptable salt thereof, or a pharmaceutical composition containing either entity, for the manufacture of a medicament for the curative or prophylactic (oral) treatment of erectile dysfunction in man."

Added Matter and Commercially Important Patents

- ◆ Covering *inter alia* the use of sildenafil citrate (Viagra[®]) to combat MED*.

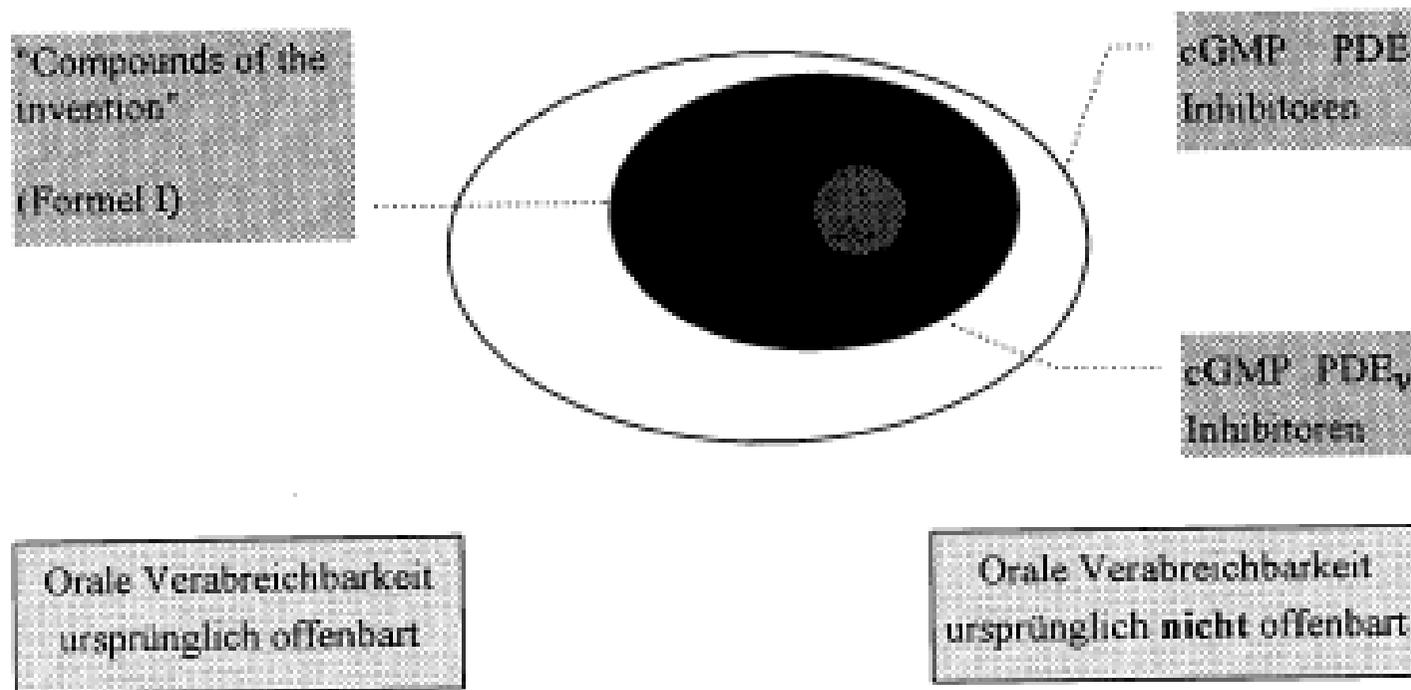


*Male Erectile Dysfunction

Pfizer's EP 702 555 B1 (Sildenafil):

- ◆ The administration of the structurally defined compounds was originally said to be oral.
- ◆ The administration of the functionally defined compounds was not originally disclosed.
- ◆ In pre-grant proceedings, the term "oral" was introduced into the broad claims directed to the use of the functionally defined compounds.

Added Matter and Commercially Important Patents



Pfizer's EP 702 555 B1 (Sildenafil):

- ◆ The word "oral" in claim 10 was added during prosecution.
- ◆ Opponents realised that this adds new matter.
- ◆ Functional claims 10 and 11 lost in the inescapable trap.
- ◆ Pfizer's argument that the disclosed administration method applied to both kinds of teaching failed to convince the Appeal Board.



First Lesson

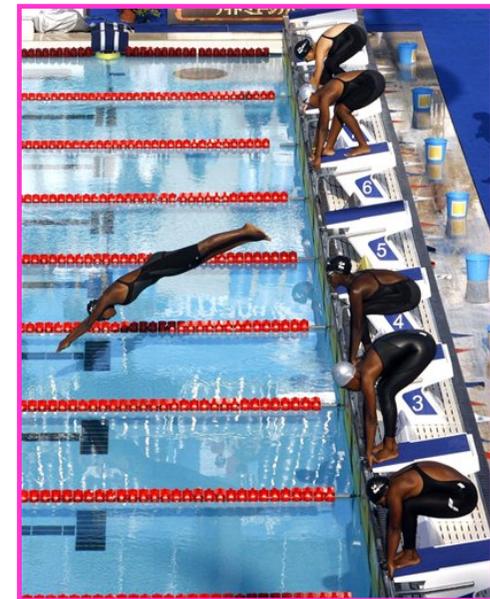
- Draft your patent application diligently, e.g. describe all possible combinations of features
- Don't rely on Examiner's assessment, but critically assess your amendments yourself



Basic Legal Principles

Introduction

- Which amendments are admissible?
- General Principles :
 - Applicant should not be allowed any **unfair advantage** when amending
 - Third parties must have legal certainty
- These principles are embodied in Art 123 EPC (see also G1/93)



Basic Legal Principles

Relevant Legal Provisions

- Art 123(2) EPC:

*The European patent application or European patent may not be amended in such a way that it contains **subject-matter which extends beyond the content** of the application as filed.*

- Art 123(3) EPC:

*The European patent may not be amended in such a way as to **extend the scope of protection**.*



Basic Legal Principles

G3/89 and G11/91

*Any amendment to parts of a European patent application or of a European patent relating to the disclosure (the description, claims and drawings) is subject to the mandatory prohibition on extension laid down in Art. 123(2) EPC and can therefore, irrespective of the context the amendment made, only be made **within the limits of what a skilled person would derive directly and unambiguously, using common general knowledge**, and seen objectively and relative to the date of filing, from the whole of these documents as filed.*

Basic Legal Principles

G2/98 and G1/03: The uniform concept of disclosure

The same criteria for assessing

- *Allowability of an amendment (relevant disclosure: application as filed)*
- *Validity of a priority claim (relevant disclosure: priority document)*
- *Novelty (relevant disclosure: prior art document)*

Basic Legal Principles

G2/10 of Aug. 30, 2011 confirms prior G decisions and re-emphasises the need for technical assessment

*Whether **the skilled person** is presented with new information depends on how he or she would understand the amended claim, i.e. the subject-matter remaining in the amended claim and on whether, using **common general knowledge**, he or she would regard that subject-matter as **at least implicitly disclosed in the application as filed**....*

...what is required is an assessment of the overall technical circumstances of the individual case under consideration...

Basic Legal Principles

The Skilled Person: Who is He or She?

- Presumed to be an ordinary practitioner aware of what was common general knowledge in the art at the relevant date (C-IV, 9.6).
- Does not possess inventive capability (T39/93).
- May be a group of people (T141/87; T99/89).
- He or she reads the application with a mind willing to understand (T199/90)

Basic Legal Principles

Common General Knowledge

HERBICIDE / ICI - T206/83

It is normally accepted that common general knowledge is represented by basic handbooks and textbooks on the subject in question.

What else constitutes common general knowledge?

Basic Legal Principles

Common General Knowledge

CHIMERIC GENE / BAYER - T890/02

The Board addressed whether the enzyme and EMBL databases may be considered as common general knowledge available to the skilled person.

In light of case law, the Board addressed three important aspects for correctly assessing the common general knowledge of the skilled person.

Basic Legal Principles

Common General Knowledge

CHIMERIC GENE / BAYER - T890/02

- 1) Source is known to the skilled person as an **adequate source for obtaining the required information**,
- 2) Source is one from which the required information may be retrieved **without undue burden**, and
- 3) Source is one which provides the required information in a **straightforward and unambiguous manner** without any need for supplementary searches.

Basic Legal Principles

Added matter vs. Sufficiency of disclosure

- No added matter: the skilled person, using his common general knowledge, can derive **directly and unambiguously** the subject-matter of the amended claim from the application as filed.
- Sufficiency of disclosure: the skilled person, using his common general knowledge, can reproduce the subject-matter of the (amended) claim on the basis of the application as filed **without undue burden**.

Basic Legal Principles

The Application as Filed

- The application as filed **includes**:
 - The description, claims and drawings (G3/89)
 - Refers to the original language text, also of a PCT Application (Art. 70(2) EPC)
 - In exceptional circumstances, also cross-referenced documents mentioned in the specification are included (T689/90)



Basic Legal Principles

The Application as Filed

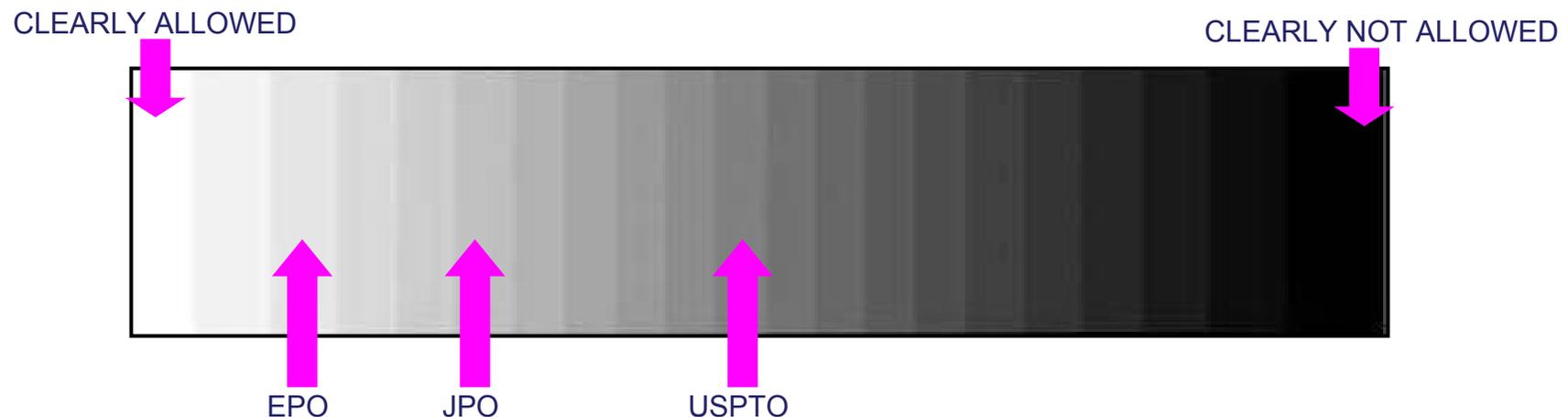
- The application as filed **does not include**:
 - The abstract (T246/86)
 - The priority document (T260/85)
 - Any translations later filed (Art. 70(2) EPC)
 - Claims filed later (R 57 and 58 EPC)
 - Other applications based on the same priority
 - The parent application (in case of a divisional)



Basic Legal Principles

Explicit and Implicit Disclosure

- No requirement to use the exact wording from the application as filed.
- Amendments can be based on explicit or implicit disclosure.
- Implicit disclosure: the clear and unambiguous consequence of what is explicitly disclosed.



Second Lesson

The allowability of an amendment depends on

- The skilled person and his common general knowledge
- The application as filed
- Relevant criterion: directly and unambiguously
- The amendment may also be based on an implicit disclosure



Art 123(2)/123(3) Trap

- Added subject-matter is a ground of opposition (EPO) and a ground of revocation (national law).
- What happens when an unallowable amendment is made during prosecution and the granted patent is attacked?
- Patentee has to fix the problem amendment...
- ... in a manner which does not extend the protective scope.
- This may put patentee in a trap where no option remains which ensures compliance with both 123(2) and 123(3).

Art 123(2)/123(3) Trap

Example 1 - No Escape Possible

- Original Claim: Metal
- Original disclosure: The metal may be a noble metal
- Amended Granted Claim: Gold

Art 123(2)/123(3) Trap

Example 1 - No Escape Possible



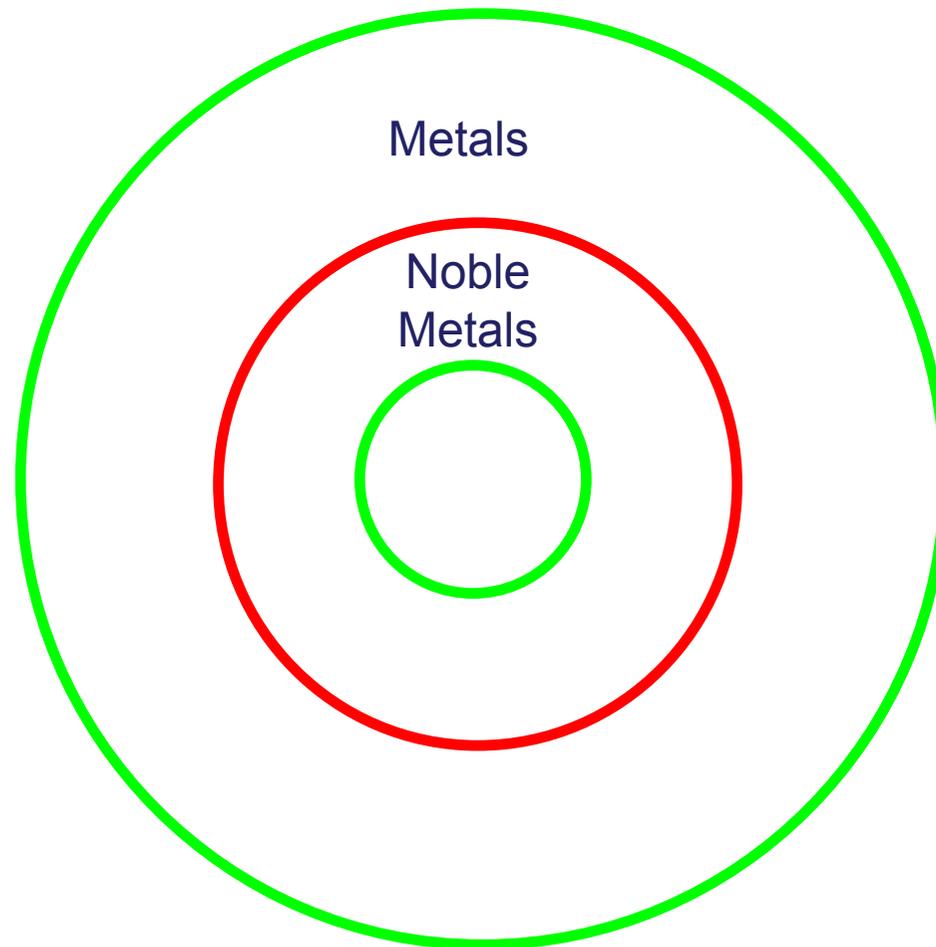
Art 123(2)/123(3) Trap

Example 2 - Escape Possible

- Original Claim: Metal
- Original disclosure: The metal may be Gold
- Amended Granted Claim: A noble metal
- Can amend further to comply with both requirements of Art 123 by restricting to gold
 - Patent can survive, but claim scope is lost

Art 123(2)/123(3) Trap

Example 2 - Escape Possible



Art 123(2)/123(3) Trap

Avoiding the Inescapable Trap

- Avoid “grey zone” amendments to protect the resulting patent from attack.
- If making a “grey zone” amendment, be aware of risks and make sure to have safe fallback position to avoid the inescapable trap.
- It is never good enough that the Examiner is convinced and grants your claim.

Amendments without support I: non-essential features

Technical Information and G1/93

A feature which had not been disclosed in the application as filed but which had been added to the application during examination is not to be considered as subject-matter which extends beyond the content of the application as filed, if it merely limits the protection conferred by the patent as granted by excluding protection for part of the subject-matter of the claimed invention as covered by the application as filed, without providing a technical contribution to the subject-matter of the claimed invention.

The fictitious skilled person vs. Real life appeal boards

- Who decides whether the amendment is directly and unambiguously disclosed? – The **skilled person** ... a beautiful but unfortunately quite fictitious creature.
- In reality, the answer is provided by an examination or opposition division or a technical board of appeal.
- These boards should simulate the skilled person ...
- ... but at times it seems that they feel more bound to earlier case law, EPO guidelines and the principle of legal certainty that underlies Art. 123(2) EPC than to the concept of a “skilled” person.

The fictitious skilled person vs. Real life appeal boards

T2017/07 – A New (and Worrying) Trend

- Original application

A hair dye composition which comprises

(A) an acid dye and

(B) an alkylene carbonate having 3-5 carbon atoms in total, ... wherein the content of the alkylene carbonate having 3-5 carbon atoms in total is 0.5-50% by weight. ...

Description:

The alkylene carbonate having 3-5 carbon atoms in total can be ethylene carbonate, propylene carbonate and butylene carbonate ...

The hair dye composition of the present invention may optionally contain further ingredients such as inorganic salts ...

The fictitious skilled person vs. Real life appeal boards

T2017/07

- Amended claim
 - A hair dye composition consisting of*
 - (A) *an acid dye*
 - (B) *propylene carbonate in an amount of 0.5-50% by weight*
 - (C) *optionally inorganic salts...*
- Would a skilled person understand that the same composition was disclosed in the application as filed?
- Not so, said the Board of Appeal.
 - The application as filed did not disclose the words “consisting of”
 - No disclosure that other components could also be excluded
 - Comprising and consisting of have different *legal effects*

The fictitious skilled person vs. Real life appeal boards

Does “comprising” disclose “consisting of”?

- T457/98, No. 2.1 of the Reasons:

The significance of the word "comprising" is generally interpreted such that all of the specifically mentioned features and any optional, additional and unspecified features are included, while the term "consisting of" includes only those features that are specified in the claim. Therefore, in the opinion of the Board, the term "comprising" includes the expression "consisting of" such that the amendment from the first to the latter does not result in a subject matter that goes beyond the content of the application in the originally filed version, even if there was not an explicit disclosure of this.

- Same reasoning followed in T425/98

The fictitious skilled person vs. Real life appeal boards

Does “Comprising” Disclose “Consisting of”?

- However, T1063/07 (and T2017/07) arrived at opposite conclusions:

*It is conspicuous to the board that there is no disclosure in the application as originally filed of a composition useful as an addition polymerization catalyst that is made up only of the metal complexes A1, A2 or A3 and an activating cocatalyst **and nothing else**, which is the meaning of the term "consisting of" in Claim 1. In fact, the wording "consisting of" does not appear in the application as filed. The replacement in Claim 1 of "comprising" by "consisting of" creates a **criticality** as to the presence of only the metal complexes A1, A2 or A3 and an activating cocatalyst in the composition which is not present as a sub-combination in the application as originally filed. Claim 1 of the main request therefore contains added subject-matter.*

- Has the skilled person changed over the last couple of years?

The fictitious skilled person vs. Real life appeal boards

Another Very Practical Question re T2017/07

- Amended claim (not allowed by TBA)
A hair dye composition consisting of
 - (A) *an acid dye*
 - (B) *propylene carbonate in an amount of 0.5-50% by weight*
 - (C) *optionally inorganic salts...*
- Why did applicant not amend the claim to read?
A hair dye composition comprising
 - (A) *an acid dye*
 - (B) *propylene carbonate in an amount of 0.5-50% by weight*

The fictitious skilled person vs. Real life appeal boards

The Answer is: He tried...

- **Applicant's claim**

A hair dye composition which comprises

(A) an acid dye

*(B) an alkylene carbonate having 3-5 carbon atoms in total, ...
wherein the content of the alkylene carbonate having 3-5 carbon
atoms in total is 0.5-50% by weight, **wherein the alkylene carbonate
is propylene carbonate***

- **Claim 1 as granted**

A hair dye composition which comprises

(A) an acid dye and

*(B) an alkylene carbonate having 3-5 carbon atoms in total, ... wherein
the content of the alkylene carbonate having 3-5 carbon atoms in
total is 0.5-50% by weight. ...*

...but the Board did not admit this claim either!

The fictitious skilled person vs. Real life appeal boards

Where Is the Catch with this Amendment?



The fictitious skilled person vs. Real life appeal boards

The Board Said, It Is here:

- Claim 1 as granted included the restriction that whenever an alkylene carbonate is present, then its amount is 0.5-50% by weight.
- In the Board's reading, claim 1 as amended only specified that propylene carbonate is present in an amount of 0.5-50% by weight.
- Hence, claim 1 as amended was no longer limited with regard to the amount of other alkylene carbonates.
- Therefore, other alkylene carbonates might now be covered by the "open" claim 1 in amounts beyond 50% by weight.
- No "one-off": reasoning confirmed in T 1312/08. However, seems to be at odds with earlier practice and T 1144/08.

The fictitious skilled person vs. Real life appeal boards

Where Does This Leave the Users of the EPO?

- When discussing Art. 123(2) EPC, most decisions do not refer to the skilled person's understanding at all.
- Legal certainty (= need for literal disclosure) seems to trump everything when it comes to Art. 123(2) EPC
- Trying to fix a missing literal disclosure by a skilled person's common general knowledge is bound to end in disaster
 - the standard is "beyond reasonable doubt" (T383/88)
 - but when has common general knowledge ever been "beyond reasonable doubt" in opposition proceedings?
- The boards are highly suspicious if the skilled person is supposed to draw the slightest inference beyond that which is literally disclosed
 - Even undisclosed combinations of disclosed preferred embodiments may be unallowable – T1410/05

Third Lesson

When drafting a new application, provide as much literal support for all possible combinations of features you can think of!



Third Lesson

- The skilled person does not seem to realize that “comprising” also includes the possibility that other components than those recited in the claim are not present.
- The skilled person understands a “consisting of” claim as implying a sort of “criticality” which must be expressly disclosed in the application as filed.
- When drafting a new application, always add a sentence that “comprising” includes the case of “consisting only of” – otherwise you may later be in trouble.



Third Lesson

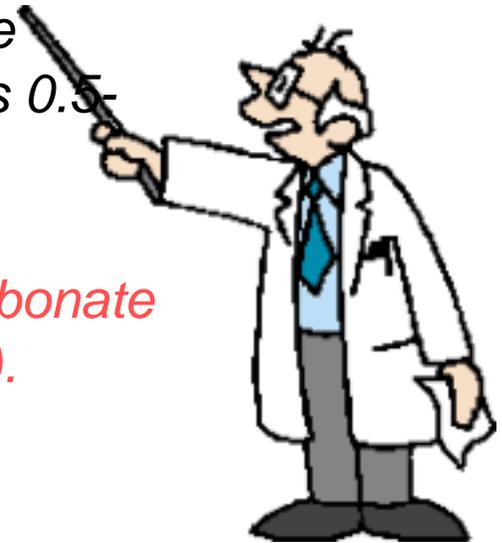
- When drafting a new application directed to a composition containing a generic ingredient A in a specific amount, provide clear support that also a specific ingredient A1 can be present in said amount without any additional ingredient A being present.

1. *A hair dye composition which comprises*

(A) an acid dye

(B) an alkylene carbonate having 3-5 carbon atoms in total, ... wherein the content of the alkylene carbonate having 3-5 carbon atoms in total is 0.5-50% by weight.

2. The hair dye composition according to claim 1, wherein the alkylene carbonate is propylene carbonate (with no other alkylene carbonate being present).



Intermediate Generalisation



- Original application no reservoir of features to artificially create new embodiments
- It is normally not admissible under Art. 123(2) EPC to extract isolated features from a set of features originally disclosed in combination. Exception: Absence of any clearly recognizable functional or structural relationship among said features
(T1067/97, T25/03)

Intermediate Generalisation

Intermediate Generalisation

- Definition of “Intermediate Generalisation” (T461/05):

Subject-matter as amended is a generalisation of a particular embodiment (originally disclosed), which is at an intermediate point between that particular embodiment and the definition in general terms of the invention as originally disclosed.

Broad disclosure	Intermediate Generalisation	Specific embodiment
A	A1+A2	A1+ A2+ A3 + A4

Intermediate Generalisation

Criteria for Allowing Intermediate Generalisations at the EPO

- Are the features of the originally disclosed combination separable or do they constitute an indissociable bloc?
- Can the skilled person recognize **without any doubt** that the features are not closely related to the other features of the working example and apply directly and unambiguously to the more general content (T962/98) (tough on applicant)?
- Some decisions more generous on applicant (e.g. T70/99, T188/05, T461/05)

Relying on Claims

- Original Claims:
 - 1. *A composition comprising a component of type A*
 - 2. *A composition according to claim 1 comprising component of type A in an amount of x to y wt.%.*
 - 3. *A composition according to claim 2 wherein the component of type A is A1.*

- Amended Claim:
 - *A composition comprising a component of type A1.*

Added matter?

Relying on Examples

- Original Claim:
 - *A composition comprising a component of type A*

- Original Disclosure:
 - *Example 1: water with 1 g/L of A1 and 10 g/L of B1*
 - *Example 2: water with 2 g/L of A2 and 5 g/L of B2*

- Amended Granted Claim Options:
 - *A composition comprising a component of type A and a component of type B*
 - *A composition comprising component A1 and component B1*
 - *A composition comprising 1 g/L of component A1 and 10 g/L of component B1*
 - *A composition consisting of water and 1 g/L of component A1 and 10 g/L of component B1*

Relying on Examples

- Original Claim:
 - *A composition comprising a component of type A*

- Original Disclosure:
 - *Example 1: water with 1 g/L of A1 and 10 g/L of B1*
 - *Example 2: water with 2 g/L of A2 and 5 g/L of B2*

- Amended Granted Claim Options:
 - *A composition comprising a component of type A and a component of type B*
 - *A composition comprising component A1 and component B1*
 - *A composition comprising 1 g/L of component A1 and 10 g/L of component B1*
 - *A composition consisting of water and 1 g/L of component A1 and 10 g/L of component B1*

Relying on Examples

Relying on Examples

- No explicit basis for expanding to **any** type and **any** amount of components A and B
- Amendment could be argued to be acceptable if omission of features from the example comply with the essentiality test:
 1. Feature to be removed not described as essential
 2. Feature to be removed is not indispensable to function
 3. Removal requires no modification of other features

Relying on Examples

T 201/83:

An amendment of a concentration range in a claim for a mixture, such as an alloy, is allowable on the basis of a particular value described in a specific example, provided the skilled man could have readily recognised this value as not so closely associated with the other features of the example as to determine the effect of that embodiment of the invention as a whole in a unique manner and to a significant degree.

Relying on Drawings

T 169/83; T523/88; T818/93:

Features from drawings can be used for claim amendments, provided the structure and the function of such features were clearly, unmistakably and fully derivable from the drawings by the skilled person.

T 305/87:

It is not permissible to combine separate items belonging to different embodiments described in one and the same document merely because they were disclosed in that one document, unless such combination had been specifically suggested there..

Relying on Drawings

T 47/03:

- Claim 1 of the Main Request:
*“A shaving aid for a razor comprising thermoplastic material and shaving aid material and means for indicating a change in the amount of shaving aid material, the means for indicating being in the form of a coating, ...characterized in that the coating is in the form of a stripe **revealing the underlying shaving aid on only two sides** of the stripe,”*
- Original Claim 1 :
“A shaving aid for a razor comprising thermoplastic material and shaving aid material, characterized that it comprises a means for indicating a change in the amount of shaving aid material.
- Original Claim 9 :
*„The shaving aid according to claim 1, wherein the means for indicating a change in the amount of shaving aid material comprises **a coating disposed in one or more segments on top of at least a portion of the shaving aid.**”*

Relying on Drawings

T 47/03:

FIG-1

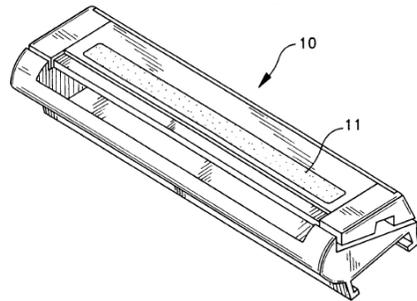


FIG-2

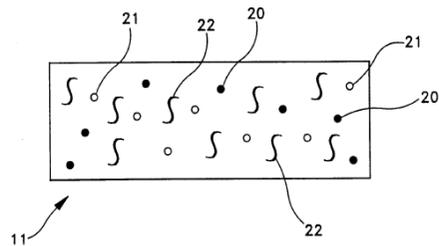


FIG-3

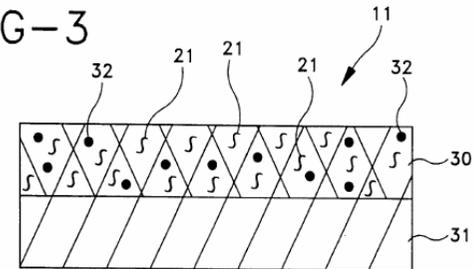


FIG-4

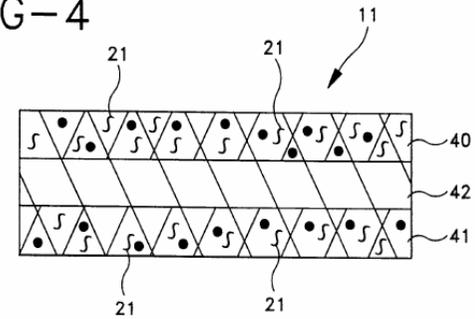
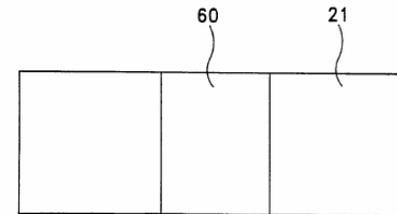


FIG-5



Relying on Drawings

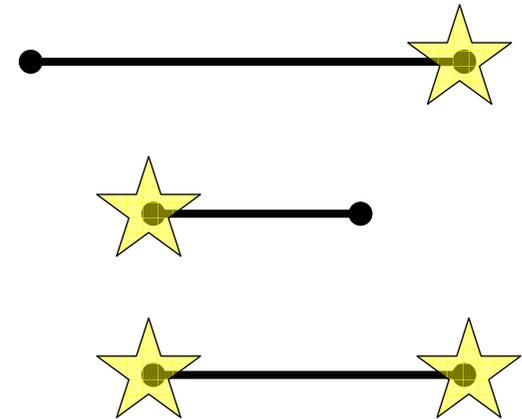
T 47/03:

Thermoplastic material only in embodiments of Figures 2 to 4, but not in Figure 5!

“In view of the above, it can only be concluded that there is a discrepancy between the subject-matter of claim 9 and the description of the embodiment of figure 5 as filed. It is, however, not unambiguously derivable from the application as filed how this discrepancy is to be resolved:...In this respect, the Board considers that the claims, description and drawings all have the same ranking and thus there is not reason to give precedence to the wording of claim 9 as filed...”

Numerical Ranges

- Original Claim:
 - *A composition comprising 2-8 % component A*
- Original Description:
 - *Preferred A content is 4-6 %*
- Amended Claim:
 - *A composition comprising 4-8 % component A*



Numerical Ranges

- Amendment allowed

T2/81 & T1170/02 – acceptable to combine one endpoint of original range with one endpoint of preferred range

Selections from Two Lists

- Original Claim:
 - *A composition comprising a component of type A and a component of type B.*
- Original Description:
 - *The component of type A is preferably A1, A2, A3 or A4.*
 - *The component of type B is preferably B1, B2, B3 or B4.*
- Amended Claim:
 - *A composition comprising A2 and B3.*

Selections from Two Lists

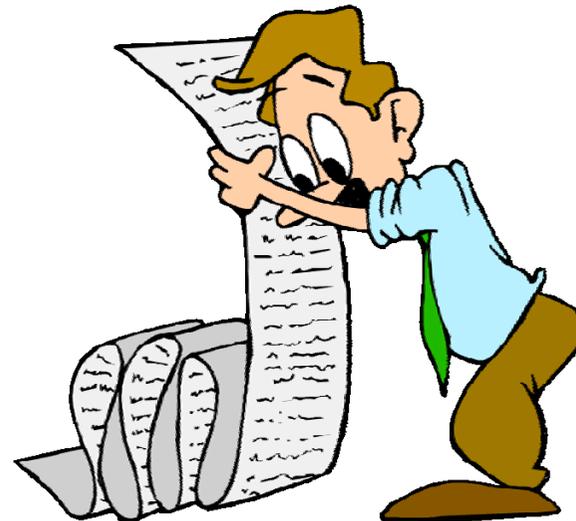
- T12/81

If **two** classes of starting substances are required to prepare end products and examples of individual entities in each class are given **in two lists of some length**, then a substance resulting from the reaction of a specific pair from the two lists **can** nevertheless be regarded for patent purposes as a **selection** and hence new.

Selections from Two Lists

- **Amendment not allowed**

T686/99 – selections from multiple lists of some length generates a new embodiment which is not part of the disclosure of the document.



Selections from Two Lists

T783/09 of January 25, 2011 (3.3.04)

Novartis's EP 1 248 604 B1 (Antidiabetic composition):

➤ Claim 1:

*“Combination comprising dipeptidylpeptidase-IV-inhibitor **which is (S)-1-(3)hydroxy-1-adamantyl)acetyl-2-cyano-pyrrolidone**, in free form or in acid addition salt form, and at least one further antidiabetic compound **which is pioglitazone, rosglitazone or troglitazone** or the pharmaceutically acceptable salt of such a compound.”*

T783/09 of January 25, 2011 (3.3.04)

- Given the word „can“ in the citation from decision T12/81, the absence of a direct and unambiguous disclosure for individualised subject-matter is **not a mandatory consequence** of its presentation as elements of lists. Thus, the „disclosure status“ of subject-matter individualised from lists **has to be determined according to the circumstances of each specific case** by ultimately answering the question whether or not the skilled person would clearly and unambiguously derive the subject-matter at issue from the document as a whole.

Selections from Two Lists

MSD's EP 1 175 904 B1 (Alendronate; T 1710/09; 3.3.02) of April 12, 2011:

➤ Claim 1:

*"The use of a alendronate in the manufacture of a medicament for treating osteoporosis in a human in need of such treatment, where said medicament is orally administered to said human **in the form of a tablet** as a unit dosage comprising about **70 mg** of the alendronate compound, on an alendronic acid active weight basis, according to a continuous schedule having a **once-weekly dosing interval**."*

Selections from Two Lists

MSD's EP 1 175 904 B1 (Alendronate; T 1710/09; 3.3.02) of April 12, 2011:

- „can“ has to be interpreted as „is to“ following standing jurisprudence
- „In view of the implications of freely interpreting this word „can“, there is a deep concern that in this way the uniformity of the disclosure assessment process cannot be warranted.“

Selections from Two Lists

T1410/05:

- Claim: Ester compound as a base oil for a lubricating oil, defined by a specific viscosity, acid value, and hydroxyl value.
- Each of the claimed values of these parameters are stated to be preferred.
- No express statement that a combination of these values is preferred.
- However, in the best examples, they are present in combination.

Selections from Two Lists

T1410/05:

- “The fresh combination of features results in the defining of a particular group of ester compounds which was not identified originally.
- ...“the application is at variance with this argumentation since the examples show that preferred parameters are also combined with less preferred parameters.”
- „That all preferred features of the invention are automatically to be read in combination is thus, neither explicitly nor implicitly, disclosed in the application as filed“.

Selections from Two Lists

The Killer Argument Is ...



- But is cherry picking (selective reading-out of information) not something that any real-world skilled person automatically does (to some extent) when reading a document?
- When a document discloses three features A, B, C in combination and one preferred embodiment A', B', C' for each feature, would a skilled person conclude that a combination of these preferred features is not part of the disclosure of the teaching of this document?

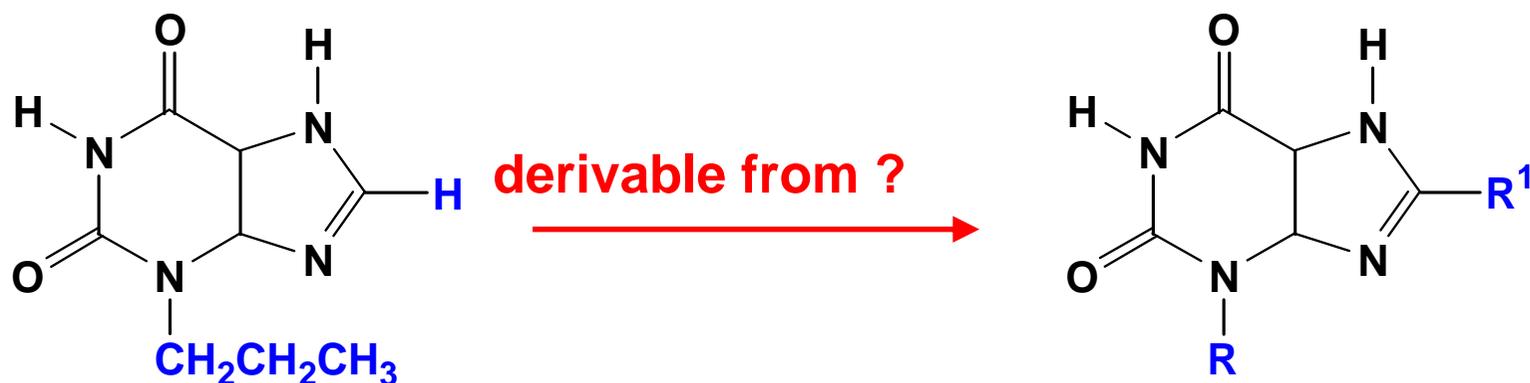
Selections from Two Lists

T490/07 (Tough on Patentee)

- *“The expression of a preference does not render an embodiment mandatory or inevitable – it merely suggests to the skilled reader that this embodiment may be [...] obvious.”*

Markush formulae

T 7/86 (Xanthines/Draco)



Application

Prior Art

In the prior art R = methyl, ethyl, propyl, butyl or lower alkyl
 R^1 = H or lower alkyl

Markush formulae

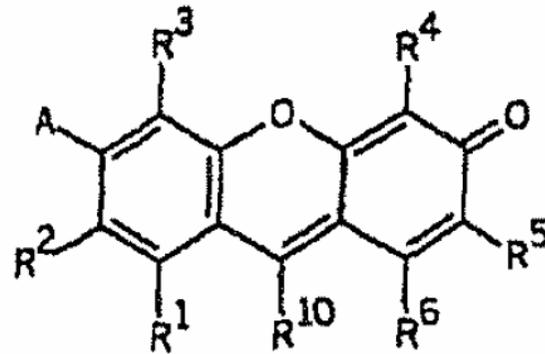
T T615/95 (Acridinium esters/Ciba Corning)

If there are three independent lists of sizeable length specifying distinct meanings for three residues in a generic chemical formula in a claim, then the deletion in each list of one originally disclosed meaning is allowable under Article 123(2) EPC if it does not result in singling out any hitherto not specifically mentioned individual compound or group of compounds, but maintains the remaining subject-matter as a generic group of compounds differing from the original group only by its smaller size. Such shrinking of the generic group of chemical compounds is not objectionable if these deletions do not lead to a particular combination of specific meanings of the respective residues which was not disclosed originally or, in other words, do not generate another invention (see no. 6 of the Reasons for the Decision).

Markush formulae

T369/07 (Fluorinated xanthene derivatives/Molecular Probes)

A compound having the formula I



wherein

R¹ and R⁶ are independently H, F, Cl, Br, I, C₁-C₁₈ alkyl or C₁-C₁₈ alkoxy;

R², R³, R⁴ and R⁵ are independently H, F, Cl, Br, I, CN; or C₁-C₁₈ alkyl, C₁-C₁₈ alkoxy or C₁-C₁₈ alkylthio, where each alkyl, alkoxy or alkylthio is optionally further substituted by F, Cl, Br, I, sulfonic acid, salt of sulfonic acid, carboxylic acid, a salt of carboxylic acid, a carboxylic acid ester of a C₁-C₆ alcohol, a carboxylic acid ester of -CH₂-O-(C=O)-R¹⁸ where R¹⁸ is a C₁-C₆ alkyl, or amino, alkylamino, dialkylamino, or alkoxy, the alkyl portions of which independently have 1-6 carbons; or one or both of R³ and R⁴ are -CH₂N(CR¹⁹HCOOR¹⁷)₂, where R¹⁹ is H or a C₁-C₆ alkyl, R¹⁷ is H, a biologically compatible counterion, a linear or branched alkyl having 1-6 carbons, or -CH₂-O-(C=O)-R¹⁸;

A is OR⁷,

where each R⁷ is independently H; C₁-C₁₈ alkyl; a C₁-C₁₈ acyl that is optionally substituted by amino, hydroxy,

Markush formulae

T369/07 (Fluorinated xanthene derivatives/Molecular Probes)

New Claim 1 is supported as follows:

- The reference to Formula II, and thus to R11 was deleted.

A deletion of one of two alternatives (alternative formulae) is allowable under Art. 123(2) EPC.

- R2 and R5 are defined to be F.

According to granted Claim 3, R2 and R5 and/or R3 and R4 are F. Thus, there is clear support for R2 and R5 being F when R3 and R4 are not F. This is in line with the original disclosure on page 6, lines 28 and 29.

- From the list of substituents R3 and R4, F, alkoxy and alkylthio were deleted.

By deleting only these potential substituents, R3 and R4 maintain their generic character. Such a deletion of individual substituents from a longer lists of substituents does not contravene Art. 123(2) EPC (see T615/95 – Acridinium Esters / Ciba Corning).

- R3 or R4 (and of course also R2 and R5) may no longer be –L-Rx or –L-Sc.

Again, the deletion of individual substituents from a longer lists of substituents does not contravene Art. 123(2) EPC (see T615/95 – Acridinium Esters / Ciba Corning).

Consequently, the new claims should be held to fulfil the requirement of Art. 123(2) EPC.

-> Accepted by the Board!

Markush formulae

Relevant EPO Case Law

Conclusion:

- **Deleting individual embodiments** of different lists is **admissible**, if the remaining combination is directly and unambiguously derivable from the application as filed,
- without additional disclosure, **limiting** two independent lists **to a single meaning** each **is not admissible**.

Disclaimers – 3 Scenarios

- Original Claim:
 - *A composition comprising a component of type A.*

- Amended claim:
 - *A composition comprising a component of type A, with the proviso that no component of type X is contained.*
 - 1) Application as filed discloses the preferred absence of type X
 - 2) Application as filed has no mention of type X at all
 - 3) Application as filed discloses type X as preferred additional component

Disclaimers – Situation #1

- Application as filed discloses the preferred absence of type X

Amendment allowable

Disclaimers – Situation #2

- Application as filed has no mention of component type X at all
 - No basis for amended claim in the application as filed – **undisclosed disclaimer**
 - However, the amended claim is deemed to comply with Art 123(2) EPC under certain circumstances
 - These circumstances are set out in G1/03

G1/03

- Undisclosed disclaimers can be used to:
 - Restore novelty over a 54(3) document (pre-filed, post-published EP applications)
 - Restore novelty over an accidental anticipation (T14/01)
 - Remove matter which is non-patentable for non-technical reasons
 - T1213/05: List not exhaustive; disclaimer to restore priority
- Conditions:
 - Should not remove more than necessary
 - Disclaimer cannot be relevant to inventive step
 - Resulting claim must be clear

Undisclosed Disclaimer Example

- Original Claim:
 - *A composition comprising a component of type A.*
- 54(3) disclosure:
 - *A composition consisting of: water, 5 g/L CO₂, 8 g/L sugar and 1 g/L component A9.*
- Amended claim:
 - *A composition comprising a component of type A, with the proviso that the component of type A is not component A9.*

Disclaimer Worded Too Broadly

- **Amendment not allowed**
- Disclaimer too broad – excludes also embodiments not disclosed in the prior art
 - Disclaims non-carbonated compositions
 - Disclaims sugar-free compositions
- Always try to copy language from the novelty-destroying document

Disclaimer Worded Correctly

- Original Claim:
 - *A composition comprising a component of type A.*
- 54(3) disclosure:
 - *A composition consisting of: water, 5 g/L CO₂, 8 g/L sugar and 1 g/L component A9.*
- Amended claim:
 - *A composition comprising a component of type A, with the proviso that the composition is not one consisting of: water, 5 g/L CO₂, 8 g/L sugar and 1 g/L of component A9.*

(see T 1194/06)

Disclaimers

Disclaimers – Situation #3

- Application as filed discloses flavour X as preferred additional component
- Case law conflict:
- T4/80, T278/88, GL-C-III-4.12: YES
- T1102/00, T1050/99: NO
- Internal EPO Guideline: NO
- T1107/06: YES
- Referral to Enlarged Board has been made (G 2/10)

Disclaimers

T 1107/06 allowed disclaimer for disclosed subject-matter

Claims allowed by Opposition Division:

1. The use of a botulinum toxin for the manufacture of a medicament for the reduction of a cholinergic controlled or cholinergic influenced secretion.
2. The use of a botulinum toxin according to claim 1 for the manufacture of a medicament for the treatment of **lacrimation**.

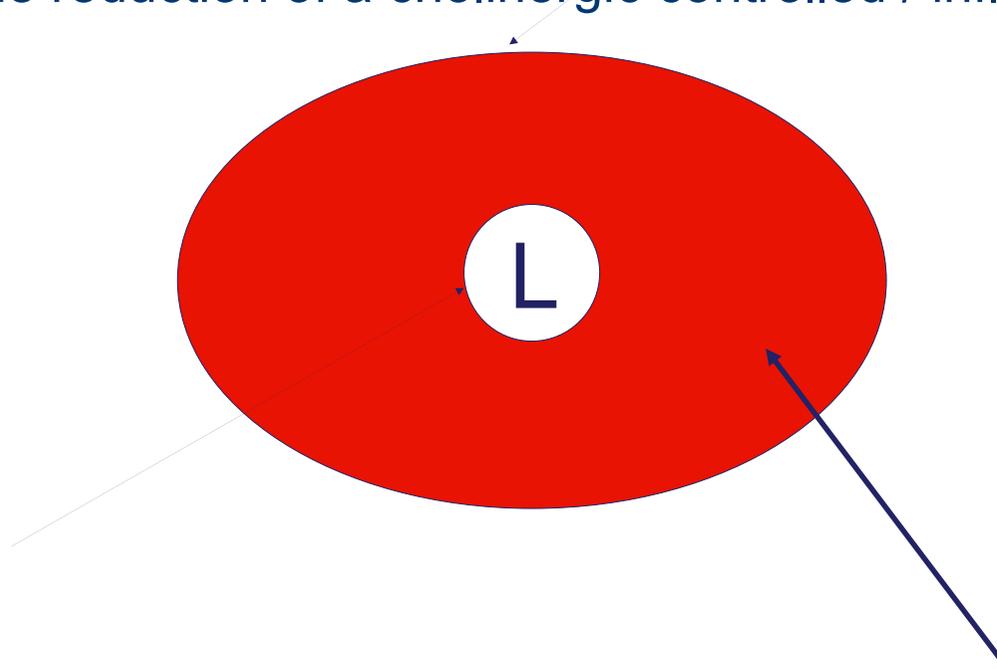
Third party observations – Amendment in appeal proceedings

1. The use of a botulinum toxin for the manufacture of a medicament for the reduction of a cholinergic controlled or cholinergic influenced secretion, wherein the secretion is **not** lacrimation.

Disclaimers

Generic:

use for the reduction of a cholinergic controlled / influenced secretion



BoA in T1107/06: the non-exemplified or non-preferred embodiments are thus implicitly disclosed as the logical complement of the exemplified or preferred embodiments.

Disclaimers

Current EPO approach more restrictive
(e.g. T 1102/00, T 1050/99, T 795/05):

- it cannot be inferred from the original disclosure that applicant intended to exclude the subject-matter of the disclaimer from the scope of protection
⇒ the criteria of G1/03 also apply to disclaimers for disclosed subject-matter.
- T 1068/07 – **Question** referred to the Enlarged BoA
“Does a disclaimer infringe Art. 123(2) EPC if its subject-matter was disclosed as an embodiment of the invention in the application as filed?”

Disclaimers

... and the answer is:

- 1a An amendment to a claim by the introduction of a disclaimer disclaiming from it subject-matter disclosed in the application as filed infringes Article 123(2) EPC if the subject-matter remaining in the claim after the introduction of the disclaimer is not, be it explicitly or implicitly, directly and unambiguously disclosed to the skilled person using common general knowledge, in the application as filed.
- 1b Determining whether or not that is the case requires a technical assessment of the overall technical circumstances of the individual case under consideration, taking into account the nature and extent of the disclosure in the application as filed, the nature and extent of the disclaimed subject-matter and its relationship with the subject-matter remaining in the claim after the amendment.

Disclaimers



Disclaimers

The Enlarged Board of Appeal has ruled:

- The criteria set out in G1/03 were not meant to apply to disclaimers for disclosed subject-matter
- It does not matter that the disclaimed subject-matter was not presented in the application as filed as subject-matter to be excluded ('intention issue')



Ü More opportunities in the future to use disclaimers for amending a claim

Disclaimers

Will all disclaimers for disclosed subject-matter be allowable?

- Enlarged Board of Appeal: NO!



- Logical complement approach of T1107/06 is not always applicable

The Concerns of the Enlarged Board of Appeal (I)

- It cannot be excluded that the disclaimer modifies the subject-matter remaining in the claim – “no presentation of new technical information”

The Concerns of the Enlarged Board of Appeal (II)

- **Distinction between disclaiming**

1. Specific embodiments
2. Whole area or subclass

Option 2 may modify the information content

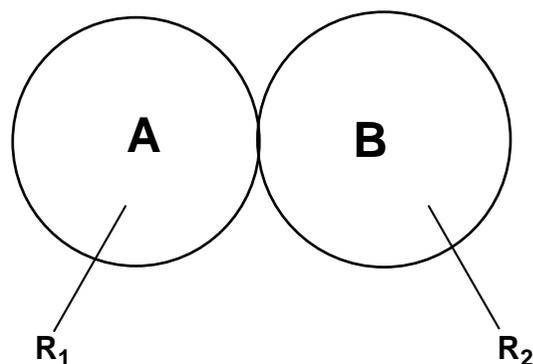
- **Examples for option 2**

Disclaimer limits the claim to intermediate generalization, subgroups or else which cannot be regarded as disclosed in the application as filed

Disclaimers

The Concerns of the Enlarged Board of Appeal (III)

Reference to T 615/95 (Acridium esters) – shrinking of lists



wherein

$\left. \begin{array}{l} R_1 \text{ is } a_1, a_2, a_3, \dots \text{ or } a_{10} \\ R_2 \text{ is } b_1, b_2, b_3, \dots \text{ or } b_8 \end{array} \right\} \text{ discloses } \begin{array}{l} R_1 \text{ is } a_2 \text{ to } a_{10} \\ R_2 \text{ is } b_2 \text{ to } b_8 \end{array}$

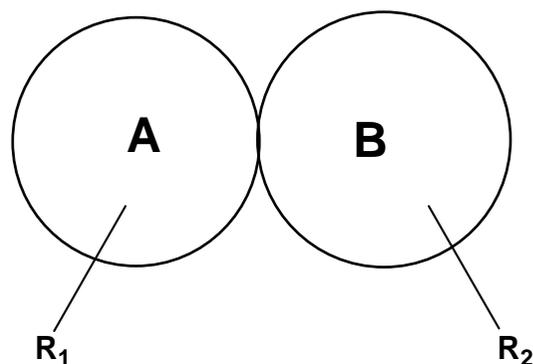
Disclaimer admissible?:

provided that R₁ is not a₂ to a₁₀ and R₂ is not b₂ to b₈

Disclaimers

The Concerns of the Enlarged Board of Appeal (III)

Reference to T 615/95 (Acridium esters) – shrinking of lists



wherein

R_1 is a1, ~~a2, a3, ... or a10~~ } discloses R_1 is a2 to a10
 R_2 is b1, ~~b2, b3, ... or b8~~ } R_2 is b2 to b8

Disclaimer admissible?:

provided that R_1 is not a2 to a10 and R_2 is not b2 to b8

→ combination a1 + b1 (“singled out”)

The Concerns of the Enlarged Board of Appeal (III) (cont.)

- Disclaimer must not result in singling out any hitherto not specifically mentioned or at least implicitly disclosed individual compound or group of compounds, or must not lead to a particular meaning of the remaining claimed subject-matter which was not originally disclosed.

Disclaimers

What seems to be allowable (again):

- Disclaiming “specific” embodiments

Example 1)

- Disclosure: “the claimed composition may also contain filler” é
- Amendment: the composition does not contain filler

Example 2)

- Disclaiming lead compound(s) from Markush formula

Legitimate interest of Applicant

- Entitled not to claim protection for an embodiment or even a part of the disclosed invention
- To avoid double patenting objection
- To obtain first quicker protection for a preferred embodiment

BUT ...

- Criteria set out in G2/10 difficult to handle
⇒ ample room for interpretation

G11/91

- 1. The parts of a European patent application or of a European patent relating to the disclosure (the description, claims and drawings) may be corrected under Rule 88, second sentence, EPC only within the limits of what a skilled person would derive directly and unambiguously, using common general knowledge, and seen objectively and relative to the date of filing, from the whole of these documents as filed. Such a correction is of a strictly declaratory nature and thus does not infringe the prohibition of extension under Article 123(2) EPC.
- 2. Evidence of what was common general knowledge on the date of filing may be furnished in connection with an admissible request for correction in any suitable form.

T881/02

➤ Claim 1:

“A biodegradable cellulose ester composition comprising...characterized in that said cellulose ester has a 4-week decomposition rate of not less than 60 wt.% as determined using the amount of evolved carbon dioxide as an indicator in accordance with ASTM D5209-91 (ASTM 125209-91).”

Opposition Division:

- *Obvious error!*
- *ASTM D5209-91 is the only ASTM standard for establishing a biodecomposition rate the OD is aware of.*

T881/02

The Appeal Board held

- No evidence had been submitted in order to establish that no ASTM with a 6 digit number existed before the priority date
- Publications of ASTM standards not relevant since they do not reflect common general knowledge
- No evidence had been submitted by the Respondent to show that the mentioned ASTM standard belonged to the common general knowledge and, even if this would have been the case, tht this standard was the only one used.
- Opposition Division's statement cannot be used to prove common general knowledge either.

Pre-grant amendments

Rule 137(4) EPC

- *Amended claims may not relate to unsearched subject-matter which does not combine with the originally claimed invention or group of inventions to form a single general inventive concept*
- This can cause problems when broadening or shifting the claim scope

Amendments After Grant

- Limitation Proceedings
- Opposition Proceedings

Amendments After Grant

Amendment During Opposition

- Relevant Articles and Rules:
- Art 123(2) EPC: No added matter
- Art 123(3) EPC: No extension of scope
- R 80 EPC: Amendment must be occasioned by a ground of opposition
- Amendments must be filed in time, otherwise they may not be admitted into the proceedings

Amendments After Grant

Change of Claim Category

- Product to Process YES (T5/90)
- Product-by-process to Process YES (T423/89)
- Product to Use YES (G2/88)

- Process to Product NO (T20/94)
- Process to Product-by-process NO (T20/94)

- Liquid composition to Packaged kit containing syringe pre-filled with liquid composition
NO (T1898/07)

Amendments After Grant

Conclusions

Compliance with Art 123 is crucial during prosecution

- Non-compliance is a ground of opposition & revocation
- Inescapable trap is a **danger** to patentee
- Avoid questionable amendments if possible, or at least make sure there is a further fallback position within the amended claim



THANK YOU FOR YOUR ATTENTION

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