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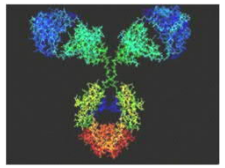
Amendments to the “Guidelines for Examination” in the EPO as of March 1, 2021

JIPA Video Monthly Meeting, August 2021

Dr. Jürgen Meier


事務所概要

VOSSIUS は

弁理士、弁護士のパートナー制事務所であり、

ミュンヘン、デュッセルドルフ、ベルリン、バーゼルに事務所を構え、

世界各国に顧客を有し、欧州の中でも代表的な知的財産事務所の一つです。

アジアチーム

弊所のアジア担当弁理士、コンサルタントは
日本語、マンダリン、韓国語といったアジア各国言語に精通し、
お客様の複雑な法律問題に関するコミュニケーションを容易にします。

Main Changes in the new “Guidelines”

1. Gender neutrality (e.g. H-II, 3.4 or E-IX, 2.3.4)
   → plural used: “applicants”; “proprietors” → “they”
2. Unity harmonization with national offices (F-V, 3)
3. Examples for Claim Formulations for Computer-Implemented Inventions requiring additional Devices or specific Data Processing Means (F-IV, 3.9.2)
4. Antibody Patenting and Requirements on how an Antibody needs to be defined (G-II, 5.6)
5. Description Amendments before Grant (H-V, 2.7; F-IV, 4.3)
   → Embodiments that are not covered by amended claims have to be removed unless they are considered useful for emphasizing specific aspects of the invention and are clearly marked as such
   → Examiner may reject the case based on an (alleged) insufficient “adaptation” of description
6. Procedures for Videoconferencing/Oral Proceedings (e.g., E-III, 8.5.2)
   → also filing of written submission via e-mail

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Unity
(F-V, 3; F-V, 3.3.1)

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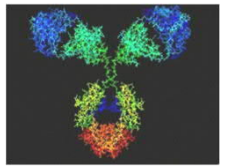


Unity – F-V, 3

- harmonization with national, European approaches
- if a lack of unity is established, claims are to be grouped based on their technical relationship

Unity – F-V, 3.3.1

- Explanations of the minimum reasoning the Examiner has to provide

  – "common matter"
  – "why this common matter cannot provide a single, general inventive concept" (based on prior art or general knowledge)
  – "why is there no technical relationship"

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Computer Implementing Inventions (CII)
Patentability of Data Base Management Systems
(F-IV, 3.9.2; G-II, 3.6.4)

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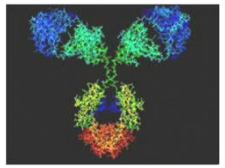


CII

- Section addresses requirements in
  (i) claims defining devices for carrying out computer-implemented methods ("computer claims") and
  (ii) claims defining a computer program that causes a computer to carry out certain method steps ("computer program claims").
- Where the computer-implemented method cannot be fully performed by generic computer means but instead requires "specific technical means" (e.g., a certain type of sensor), the computer and computer program claims must define the device (computer) as including these "special technical means".
- New: If the method defines a further processing of data by generic computational means, it is not required to define the specific technical means in the computer or computer program claim.

Example 1 – CII requiring specific technical means

In this example, the method claim comprises a step which is defined as being executed by specific technical means (here: an electromagnetic detector in a pulse oximeter).

Example 1

Claims:

1. A method of determining oxygen saturation in blood in a pulse oximeter, comprising:

   – receiving in an electromagnetic detector first and second electromagnetic radiation signals from a blood-perfused tissue portion corresponding to two different wavelengths of light;

   – normalizing said electromagnetic signals according to steps A, B and C to provide normalised electromagnetic signals;

   – determining oxygen saturation based on said normalized electromagnetic signals according to steps D and E.

Example 1 (ff)

2. A pulse oximeter having an electromagnetic detector and means adapted to execute the steps of the method of claim 1.

3. A computer program [product] comprising instructions to cause the device of claim 2 to execute the steps of the method of claim 1.

4. A computer-readable medium having stored thereon the computer program of claim 3.

→ *corresponding computer & computer program claims must recite the "pulse oximeter" and the "electromagnetic detector"*

Example 2

In this example the invention lies in the further processing of acquired data for determining the oxygen saturation in blood. The data can be received for example from a data file storing data previously acquired by, e.g. an electromagnetic detector.

Example 2 (no specific device needed)

Claims:

1. A computer-implemented method of determining oxygen saturation in blood, comprising:

   – receiving data representing first and second electromagnetic radiation signals acquired by an electromagnetic detector from a blood-perfused tissue portion corresponding to two different wavelengths of light;

   – normalising the data representing said electromagnetic signals according to steps A, B and C to provide normalised data;

   – determining oxygen saturation based on said normalised data according to steps D and E.

Example 2 (ff)

2. A data processing apparatus comprising means for carrying out the method of claim 1.

3. A computer program [product] comprising instructions which, when the program is executed by a computer, cause the computer to carry out the method of claim 1.

4. A computer-readable medium having stored thereon the computer program [product] of claim 3.

→ *corresponding computer & computer program claims do not necessarily have to recite the "pulse oximeter" and the "electromagnetic detector" because "receiving data" can be carried out by generic data processing means*

G-II-3.6.4: Novelty and Inventive Step of Data Base Management System

- Clarifies conditions under which the features of database management systems are to be taken into account in the assessment of novelty and inventive step.
- Features specifying the internal functioning of a database management system are normally based on technical considerations and are thus to be taken into account.
- Methods relating to information retrieval that are based on cognitive or linguistic considerations, or subjective criteria may rely on non-technical distinctions. Such non-technical distinctions are not to be taken into account for the assessment of novelty and inventive step.

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Antibody Patenting
G-II, 5.6

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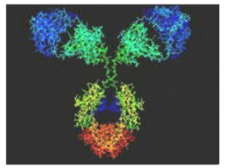



Antibody Patenting

Structural and functional features acceptable!

Antibody Patenting

In general, antibodies, i.e. conventional antibodies, recombinant antibody derivatives or new antibody formats can be defined by (but are not limited to):

(a) their own structure (amino acid sequences);

(b) nucleic acid sequences encoding the antibody;

(c) reference to the target antigen;

(d) target antigen and further functional features;

(e) functional and structural features;

(f) the production process;

(g) the epitope;

(h) the hybridoma producing the antibody. (Deposits need to be correct! Formal requirements!)

Antibody Patenting: structural features

- In conventional antibodies the definition needs to comprise:

  at least all 6 CDRs

- Exceptions and if it is experimentally shown that one or more of the six CDRs do not interact with the target epitope or if it concerns a specific antibody format allowing for epitope recognition by fewer CDRs.

- Specific antibodies may require AB framework definitions of variable regions (e.g. for antibodies that are not first in class but have improved/inventive properties)

Antibody Patenting: Definition by reference to target/target antigen

Examples of claim language (see G-II, 5.6.1.2)

- antibody binding to X;
- anti-X antibody
- antibody reacting with X;
- antibody specific for antigen X or
- antibody binding to antigen X consisting of the sequence defined by SEQ ID NO. 1, 2, 3, 4, 5, 6, … .

also negative feature possible

- “binding to antigen X but not antigen Y”

→ clear and unambiguous description necessary!!!

Antibody Patenting: Definition by further functional features

Examples:

- binding affinity
- neutralizing properties
- induction of biological process (e.g. apoptosis)
- internalization of receptors
- inhibition or activation of receptor
- etc.

CAVE: “unusual parameters”:

- alleged that this disguises lack of novelty
- burden of proof on applicant!!!
- Unambiguous test in the description necessary

  → identify all necessary parameters! Software??

Contents

T 3196/19, "Anti-PD-1 antibody/DANA-FABER GENETICS INSTITUTE“
on “functional features”

T 3196/19, "Anti-PD-1 antibody/DANA-FABER GENETICS INSTITUTE"

Claim 1:

1. An anti-human PD-1 antibody that inhibits signaling via PD-1 by inhibiting the interaction of human PD-1 and human B7-4, which is a human protein comprising the amino acid sequence shown in figure 3 or 4, for use in the treatment of a condition that would benefit from upregulation of an immune response, wherein the said condition is a tumour.

T 3196/19, "Anti-PD-1 antibody/DANA-FABER GENETICS INSTITUTE"

The Board denied support of the claim by the application as filed:

6.4 The board observes that the group of agents disclosed on page 4 for upregulating the immune response by inhibiting the signaling *via* PD-1 is much larger and, except for one agent (a soluble form of PD-1), different from the agents described for use in the treatment of a subject having the specific conditions cited further down on the same page including a tumour. There is neither an indication that each agent of the larger group must be necessarily suitable for every condition cited on the same page, nor a suggestion that a blocking anti-PD-1 antibody could be selected from the larger group of agents for being a suitable agent for the treatment of one of the specific conditions cited on that page, namely a tumour. Moreover, although the blocking anti-PD-1 antibody is defined as inhibiting the signaling *via* PD-1, there is neither a hint nor an indication of the mechanism underlying said inhibition. This mechanism could involve modulation of the interaction between PD-1 and B7-4 and, more particularly, inhibition of said interaction, but is not necessarily limited thereto. Likewise, there is no indication that the non-activating anti-PD-1 antibody disclosed on page 9 modulates the interaction of PD-1 and B7-4, let alone inhibits said interaction. It may be so, but there are also many other possible mechanisms that may result in non-activation or inhibition of the signaling *via* PD-1. Moreover, there is no reference in the disclosure on page 9 to the treatment of any specific condition, let alone of a tumour.

T 3196/19, "Anti-PD-1 antibody/DANA-FABER GENETICS INSTITUTE"

The Board denied support of the claim by the application as filed:

7.4 The board observes that the functional definition on page 85 characterises a generic group of agents and that the sole example of specific agents disclosed in this context are the soluble forms of PD-1 or B7-4, but not any anti-PD-1 antibody. ...

11. It may be that the claimed anti-PD-1 antibodies are rendered obvious by the disclosure of the earlier patent application, either alone or in combination with the whole knowledge on the CTLA4 inhibitory receptor available from the prior art and the common general knowledge of the skilled person. However, as stated above, this is not the criterion set out in the established case law for assessing whether or not the claimed subject-matter contravenes Articles 76(1) and 123(2) EPC [impermissible broadening]. The relevant criterion is set out in decision G 2/10 (*supra*), namely the gold standard, and in the present case, this standard is not met by the claimed subject-matter, as shown by all considerations made above.

None of the Auxiliary Requests was able to overcome the problem!

Contents

T 2332/10, "Antibody to C5 and C5a/GENENTECH“
on “functional features”

T2332/10, “Antibody to C5 and C5a/GENENTECH”

1. An antibody or fragment thereof that binds to C5 and C5a, but does not prevent the activation of C5 and does not prevent formation of or inhibit the activity of C5b.

- Claim construction: antibody does not interfere with “convertase”.
- Novelty: the disclosure of a peptide to generate an antibody thereto does not amount to an unambiguous disclosure of an antibody to the three dimensional antigen having a particular function: section 14.1 and 14.2 of the decision.
- Inventive step, sections 20., 24. and 27.: "the assessment of inventive step is purpose driven"!

Conclusion: a broad group of antibodies can be patentable, even when directed against known antigens.

Contents

T 941/16, "anti-PSMA antibody/UNIVERSITÄTSKLINIKUM FREIBURG“
on “structural features”

T 941/16, "anti-PSMA antibody/UNIVERSITÄTSKLINIKUM FREIBURG"

Claim 1:

An isolated monoclonal antibody or an antigen binding portion thereof which

a) binds to prostate specific membrane antigen in its native form occurring on the surface of tumor cells

b) can be internalized by a tumor cell,

c) binds strongly to LNCAP cells but not or only minimally to cells which lack expression of prostate specific membrane antigen and

d) is linked to a label or a cytotoxic agent, characterized in that

e1) it comprises at least three of the CDR sequences selected from the group consisting of the CDRs designated as CDR H1, H2, H3, L1, L2 and L3 as shown in Fig. 21 or

e2) it comprises at least three of the CDR sequences selected from the group consisting of the CDRs designated as CDR H1, H2, H3, L1, L2 and L3 as shown in Figure 20.

T 941/16, "anti-PSMA antibody/UNIVERSITÄTSKLINIKUM FREIBURG"

The Board denied enablement by starting as follows:

9. In the jurisprudence regarding Article 83 EPC [enablement] it has been established that the claimed invention must be sufficiently disclosed on the relevant date of the application (see Case Law, II.C.2.), based on the application as a whole (*ibid*., II.C.3.1), in consideration of the common general knowledge of the skilled person (*ibid*., II.C.4.). At least one way of carrying out the claimed invention must be disclosed, but this disclosure is sufficient only if it allows the invention to be performed in the whole range claimed (*ibid*., II.C.5.2., II.C.5.4 and II.C.7.1.2).
   Furthermore, the disclosure must be reproducible without undue burden. Where the person skilled in the art has to find out by trial and error which compound, if any, meets the parameter set out in the claim, this constitutes an undue burden, even if it involves routine experimentation (*ibid*., II.C.6.7.).
   None of the Auxiliary Requests was able to overcome the problem!

The Board then moved to considerations regarding possible mutations required in the accompanying framework regions when making humanized antibodies, the possible necessity to retain HCDR3 for specificity, failed attempts at making humanized antibodies reported in the art, etc., ...

T 941/16, "anti-PSMA antibody/UNIVERSITÄTSKLINIKUM FREIBURG"

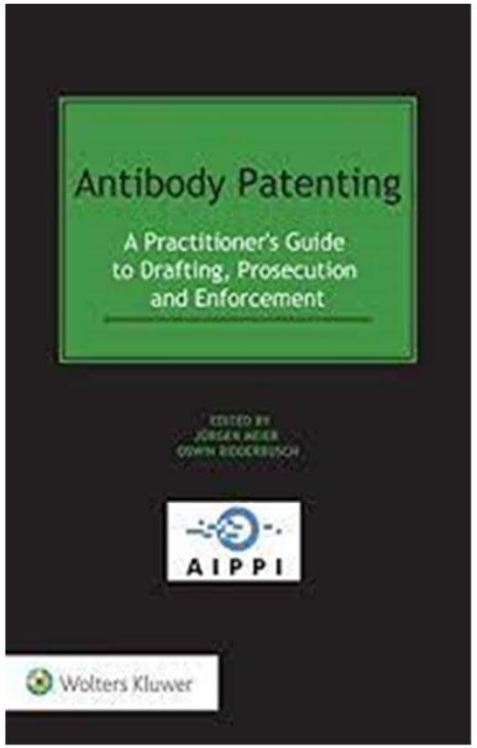
... to eventually conclude:

19. Consequently, the common general knowledge together with the experimental data set out above, cannot support the appellant's assertion that selection of any three murine CDRs was sufficient to obtain humanized antibodies/fragments retaining the functional properties indicated in claim 1. Based on the evidence on file, rather the presence of both murine CDR H3 and CDR L3, and not only one or none, seems to be necessary to reliably obtain a claimed antibody/fragment.

Applicant's appeal was dismissed.

The composition of the respective frameworks seems to have played an important role for the Board's conclusion.

Further Reading:



1st edition in **2019**

Editors: Dr. Jürgen Meier, Oswin Ridderbusch

EPO chapter: Dr. Jürgen Meier, Oswin Ridderbusch

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Adaptation of the description: the EPO's new ideas (F-IV, 4; F-IV, 4.3 (iii))

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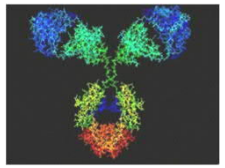



EPO Guidelines for Examination as in force since 1 March 2021

Part F, IV, 4 “Clarity and interpretation of claims” was severely modified by the EPO

Basically, F, IV, 4.3 (iii) was completely revised and newly drafted

A. New sections in GL F, IV, 4.3 (iii)

Part of the subject-matter of the description and/or drawings is not covered by the claims

Where parts of the description give the reader the impression that they disclose ways to carry out the invention but are not or, due to amendments to the claims, are no longer encompassed by the wording of the claims, these parts often throw doubt on the scope of protection and therefore render the claims unclear or unsupported under Art. 84, second sentence, or, alternatively, render the claims objectionable under Art. 84, first sentence.

The description must be adapted to the claims in order to avoid inconsistencies between the claims and the description. Embodiments in the description which are no longer covered by the independent claims must be deleted (for example if the description comprises an alternative for at least one feature which is no longer covered by the amended claims) unless these embodiments can reasonably be considered to be useful for highlighting specific aspects of the amended claims. In such a case, the fact that an embodiment is not covered by the claims must be prominently stated (T 1808/06).

(emphasis added)

Yet, in life sciences, this may not be so easy: number of claims, Art. 83 EPC, “equivalence”, etc…

T1808/06, “Oxygen-absorbing label/MULTISORB TECHNOLOGIES INC.“

Headnote:

When the description has to be amended with regard to the requirement of Article 84 EPC [clarity] that the claims have to be supported by the description, reference to Article 69(1) EPC [Extent of Protection of a European patent] as justification for a less stringent adaptation of the description is misleading insofar as it can be understood to suggest a direct applicability of its contents at the examination or opposition stage. This is clearly not the case as Article 69(1) EPC relates to the scope of protection.

It is only in situations where the removal of inconsistencies is not possible for procedural reasons (eg no amendment possible of the granted version) that - purely as an auxiliary construction - Article 69(1) EPC can be invoked for an interpretation of the claimed subject-matter.

B. New sections in GL F, IV, 4.3 (iii)

Part of the subject-matter of the description and/or drawings is not covered by the claims

For example, if the claims are amended to specify a vehicle employing electric motors but one of the embodiments in the description and drawings employs a combustion engine instead, the inconsistency can be rectified by removing the embodiment with the combustion engine from the description and drawings.

Alternatively, this embodiment must be marked as not being covered by the claimed invention (e.g. "embodiment not covered by the claimed invention"). It is not sufficient to use generic statements such as "embodiments not falling under the scope of the appended claims are to be considered merely as examples suitable for understanding the invention" without indicating which parts of the description are no longer covered.

In addition, merely changing the wording "invention" to "disclosure" and/or the wording "embodiment" to "example", "aspect" or similar is not sufficient to clearly state that this part of the description does not fall under the scope of the claimed invention. It has to be explicitly specified that this part of the description does not describe part of the claimed invention.

(emphasis added)

How these new GL are employed in the real world!

In our opinion unreasonable burden, also on international applicants.

No major jurisdiction besides the EPO has such a painstaking approach to description amendments at all!

Last but not least, the CLAIMS define the scope of the invention and also the scope of protection.

Some examiners now force applicants to delete alternative embodiments from the description even when these alternative embodiments merely characterize equivalent means for obtaining a desired technical effect end even when these embodiments are not decisive for patentability of the claims.

A recent Communication pursuant to Art. 94 (3) EPC

Datum Date Date	31.05.2021	Blatt Sheet Feuille	1	Anmelde-Nr: Application No: Demande n°:	XX XXX XXX.X

1 Note regarding the term "*present disclosure*"

Applicant maintained the term "*present disclosure*" in paragraphs [0039], [0050], [0051], [0052], [0076], [0080], [0086], [0088], [0096], [0102] and [0110] of the amended description$_{10.11.2020}$.

However, the examining division considers these terms as not meeting the requirements of **Art.84 EPC** and **R.42(1)(e) EPC** and intends to grant a patent with the term "*present disclosure*" replaced by the term "*present invention*" also in paragraphs [0039], [0050], [0051], [0052], [0076], [0080], [0086], [0088], [0096], [0102] and [0110].

This is because, these paragraphs are inconsistent (**Art.84 EPC**, **R.42(1)(e) EPC**) with amended paragraphs [0030]-[0034]$_{10.11.2020}$, which use the term "*present invention*", and since the term "*present disclosure*" is not limited to "*disclosure **of the invention***" (=title of **Art.83 EPC**) nor to the term "*the description shall describe in detail at least one way of carrying out **the invention claimed***" (=wording of **R.42(1)(e) EPC**). On the contrary, the term "*present disclosure*" is broader than and, thus, in contradiction to what is described in paragraphs [0030]-[0034]$_{10.11.2020}$, and to what is required by **Art.83 EPC** and **R.42(1)(e) EPC**. Thus, doubts arise about what is actually described in the description following the term "*present disclosure*" and whether or not it is meant to describe "*at least one way in detail of carrying out **the invention claimed***" (**R.42(1)(e) EPC**).

The likelihood that the applicant will give his consent to these amendments is considered higher than that he will not do so. Thus, for efficiency reasons, a consultation or further communication is not considered expedient. Even in the unlikely case that applicant disagrees, he still has the opportunity, under **R.71(6) EPC**, to react.

Applicant argues as follows:

EPO Form 2906 01.91TRI

A recent Communication pursuant to Art. 94 (3) EPC

Applicant respectfully disagrees with the understanding of the Search Division with regard to the term "present disclosure". This term has been replaced with "present invention" in some paragraphs enumerated by the Search Division in item 5.7 of the Search Opinion. However, the term has been maintained in the detailed description of the application. The term "present disclosure" is an adequate term to explain to the skilled reader how the invention can be carried out. Art. 83 EPC also uses the term "disclosure" in the context of enablement. The detailed description is one part of the specification that discloses the at least one way of carrying out the invention in line with the Guidelines for Examination Part FIII1. Patents are granted for inventions (Art. 52(1) EPC) and inventions are disclosed in the European Patent Application. Thus, the use of the word "disclosure" is not an attempt of "hiding" the invention "with certain strategies" (as alleged by the Search Division) but merely expresses the purpose of the detailed description. Since the term "disclosure" is used in the detailed description, there is also no inconsistency between the claims and these passages, and it is clear that these passages do not refer to the "background art" or "something else" as stated by the Search Division. Finally, Art. 84 EPC referred to by the Search Division when enumerating several passages of the description using the term "present disclosure" applies to claims and not to the description.

However, this opinion is not shared.

As already said, the title of **Art.83 EPC** is "*disclosure **of the invention***" and does not contain the term "*present disclosure*". Also **R.42(1)(e) EPC** does not contain the term "*present disclosure*" but "*the description shall describe in detail at least one way of carrying out **the invention claimed***". On the contrary, the term "*present disclosure*" is a rather broad and vague term which is, in most cases, contrary to applicant's opinion, not "*an adequate term to explain to the skilled reader how the invention can be carried out*".

Indeed, the **EPC** does not forbid the usage of the term "*present disclosure*". However, it must be clear what is actually meant thereby. In the present case this is not at all clear, i.a. since there are inconsistencies between paragraphs [0030]-[0034]$_{10.11.2020}$ and paragraphs [0039], [0050], [0051], [0052], [0076], [0080], [0086], [0088], [0096], [0102] and [0110]$_{10.11.2020}$.

Note:

Applicant is right that **Art.84 EPC** stipulates:

"*The claims shall ...*", but not "*The description shall ...*".

However, applicant is reminded to the **Guidelines F-IV-4.3** which stipulate i.a.

A recent Communication pursuant to Art. 94 (3) EPC

"***Any inconsistency*** *between the description and the claims must be avoided if it may throw doubt on the extent of protection and therefore render the claim unclear or unsupported under Art. 84, second sentence or, alternatively, render the claim objectionable under Art. 84, first sentence.*"

Further, the term "*present disclosure*" refers to everything in the patent (or patent application) and a reader of the patent (or patent application) is forced, in the absence of any clear statement in this respect, to unnecessarily spend time to determine himself whether the description following the term "*present disclosure*" is meant to be "*a description in detail of at least one way of carrying out* ***the invention claimed***" or something else. This is considered as contrary to at least **R.42(1) EPC**.

Another recent Art. 94 (3) EPC Communication:

Features of the independent claims are non optional

The technical features of the independent claims may **not be presented as optional** in the description (F-IV, 4.3 (iii)). Where they precede a feature of an independent claim, terms such as “for example“, “may“, “can”, “exemplary“, “optionally“, “preferably“, "typically" and the like must be removed from the description. Also, limitations added to the independent claims during prosecution cannot remain optional in the description.

Elements deleted during prosecution

The description must not seek protection for embodiments which have been deleted or limited in the claims **during prosecution** to comply with the EPC, or which are presented in the description as alternative ways of carrying out the invention while not covered by the claims. As indicated above, embodiments deleted in or not covered by the present claims have to be deleted in the description or must be marked as "not as claimed", etc.

Prosecution history is usually not taken into account when construing the scope of claims before national courts, and the situation has to be avoided where protection is later awarded for embodiments which were found not to comply with the EPC merely because those embodiments were left in the incompletely adapted description.

and:

"Invention", "embodiment", "disclosure" and the like

Merely replacing the terms "invention", "embodiment" or the like with "disclosure" or "example" / "aspect", respectively, is insufficient since these terms are used interchangeably in EPO case law.

More specifically, the subject-matter identified in the description by using the terms "invention", "embodiment", "aspect", "disclosure", "example" or the like needs to be strictly covered by, and in any way not extend beyond, the set of claims on file.

Embodiments which are no longer covered by the claims must be deleted, unless they can reasonably be considered to be useful for highlighting specific aspects of the amended subject-matter. If this is the case, they must be clearly marked as not being part of the present invention (T1808/06 and Guidelines F-IV, 4.3): Should the applicant desire to keep in the description "aspects", "examples" or elements of the "disclosure" outside the scope of the claims, then the fact that such an aspect / example / element of the disclosure is not covered by the claims must be prominently stated in the description (T1808/06, r.2), through clear wording such as "not part of the invention", “not according to the invention”, “not falling within the scope of the claimed subject-matter”, “not covered by the claims”, "not as claimed", or "but not claimed", immediately inserted after each instance of the "aspects", "examples" or elements of the "disclosure".

Contents

T 1399/17, “Balanced myristate-and laurate-containing edible oil/ BRANDEIS UNIVERSITY”

(Board 3.3.09, Haderlein, Rinaldi, Blumer on March 5th, 2021)

T 1399/17, “Balanced myristate-and laurate-containing edible oil/ BRANDEIS UNIVERSITY”

Claim 1

A triglyceride-based dietary fat for use in a method for limiting the level of at least one of triglycerides (TG), total cholesterol (TC) and LDL cholesterol in the plasma of a human or livestock animal, whose fatty acid composition comprises

10 to 35% by weight linoleic acid;

at least 10% by weight monounsaturated fatty acids; and

15 to 55% by weight saturated fatty acids,

wherein 10 to 45% by weight of said fatty acid composition is myristic acid (14:0) plus lauric acid (12:0) in which at least 3% of said fatty acid composition is myristic acid and at least 3% is lauric acid,

wherein said dietary fat is a blend of natural fats, and

wherein the total weight percent of fatty acids in said fatty acid composition is 100%.

OD: Claims (feature from a granted dependent claim) and adapted description fulfill the requirements of the EPC.

The Board denied clarity of the description (!) and revoked the patent.

T 1399/17, “Balanced myristate-and laurate-containing edible oil/ BRANDEIS UNIVERSITY”

The Board denied clarity of the description with the following reason:

2.2. […]. Article 84 EPC requires that the claims be supported by the description. This also applies to claims which have been amended in opposition (Article 101(3)(a) EPC). A mandatory feature of claim 1 is that the dietary fat be a blend of natural fats. However, the specification of the patent as amended in the oral proceedings does not reflect this. Therefore, it casts doubts on the scope of the claim. The following non-exhaustive examples are given:

- According to paragraph [0014], last sentence, it is not a mandatory feature but only a desirable one: "Desirably the balance of fatty acids is achieved using a blend of natural fats...".

- In paragraph [0040], it is still stated that"[p]referably" the dietary fat composition is a blend of natural fats. The entire paragraph and in particular the second sentence, in which it is discussed that the dietary fat composition "is... a structurally modified triglyceride-based dietary fat composition", does not support claim 1.

[…] (emphasis added]

T 1399/17, “Balanced myristate-and laurate-containing edible oil/ BRANDEIS UNIVERSITY”

Patentee filed an auxiliary request and deleted the feature “wherein said dietary fat is a blend of natural fats“

The Board did not accept this request under the prohibition of *reformatio in peius* (G1/99):

3.1 Claim 1 of the auxiliary request no longer requires that the dietary fat be a blend of natural fats. Thus, claim 1 is broader in scope than claim 1 of the main request.

3.2 Furthermore, appellant 2 is correct that the auxiliary request places the appealing opponents in a worse position than if they had not appealed. Therefore, this request contravenes the prohibition of reformatio in peius. According to G 1/99 (OJ EPO 2001, 381, Headnote) an exception to this principle may be made under specific circumstances. The respondent has not argued that such circumstances apply, nor are such circumstances manifest to the board.

The decision under appeal was set aside and the patent was revoked!

Contents

T 0365/14, “Glycoprotein VI/MILLENNIUM PHARMACEUTICALS“
(Board 3.3.08, Stolz, Pilat, Geschwind)

T 0365/14, “Glycoprotein VI/MILLENNIUM PHARMACEUTICALS“

Claim 6

A fusion protein comprising a first polypeptide having a glycoprotein VI (GPVI) activity, which activity is binding to collagen, wherein the first polypeptide comprises an extracellular domain of GPVI, and further comprising a second polypeptide with a heterologous amino acid sequence, wherein the first polypeptide comprises the amino acid sequence of SEQ. ID. NO. 9 or an amino acid sequence at least 85% identical to SEQ. ID. NO. 9.

The Board came to the conclusion that this claim (and a corresponding “nucleic acid” claim) contravene Art. 123 (2) EPC [impermissible broadening] due to the removal of an original definition of the term “polypeptide or nucleic acid of the invention”

T 0365/14, “Glycoprotein VI/MILLENNIUM PHARMACEUTICALS“

The Board assessed whether or not the amendments to the description performed before grant of the patent created subject matter extending beyond the content of the patent application as filed.

Patentee deleted form its patent application (page 4, lines 11 to 15) the following definition:

"The TANGO 268 proteins, fragments, derivatives, and variants thereof are collectively referred to herein as "polypeptides of the invention" or "proteins of the invention." Nucleic acid molecules encoding the polypeptides or proteins of the invention are collectively referred to as "nucleic acids of the invention."

The term "Tango 268" is an alternative designation for glycoprotein VI or GPVI mentioned in the claims.

T 0365/14, “Glycoprotein VI/MILLENNIUM PHARMACEUTICALS“

→ “TANGO 268” was the “protein of the invention”

→ Granted was “a fusion protein comprising TANGO 268”

→ BOARD CAME TO THE CONCLUSION that, due to the deletion of “TANGO 268” definition, “broadened subject-matter” is presented, namely a

Fusion protein [“protein of the invention”]

comprising a

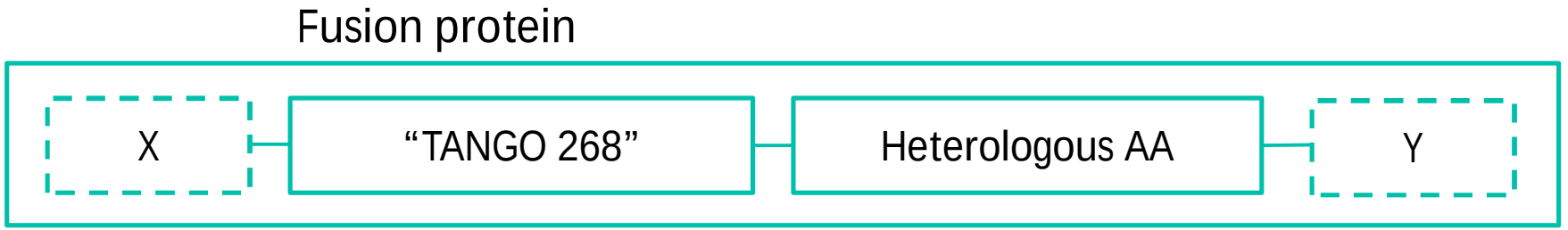
fusion protein,

comprising a protein with GPVI activity and a heterologous amino acid sequence.

T 0365/14, “Glycoprotein VI/MILLENNIUM PHARMACEUTICALS“

Intended was:

interpreted by the BOARD:



“fusion protein as the sole identifiable polypeptide of the invention”

T 0365/14, “Glycoprotein VI/MILLENNIUM PHARMACEUTICALS“

The Board denied compliance with Art. 123 (2) EPC for the following reasons:

6.2 The definition of the term "polypeptides of the invention" used in the patent application was broad and unrestricted in scope. Since the original definition of this term was removed from the description of the granted patent and no other passage defining the meaning of the term directly and unambiguously was provided, there is no longer any basis in the patent specification for interpreting it as referring to TANGO268 proteins, fragments, derivatives and variants, as proposed by appellant I [Patentee]. Thus, a skilled person reading the patent specification, especially the paragraphs describing embodiments referring to a "polypeptide of the invention", has to look for a definition of this term in the remaining parts of the patent. None of the paragraphs referring to "derivatives" and "variants" of the protein or polypeptide of the invention provide any guidance in this respect (see for instance paragraphs [0038], [0287] to [0289], [0335] of the granted patent). For this reason, the skilled person considers the claimed fusion protein as the sole identifiable polypeptide of the invention, in accordance with Rule 43(1) EPC, and construes the embodiments of the specification referring to a polypeptide of the invention to refer to it.

T 0365/14, “Glycoprotein VI/MILLENNIUM PHARMACEUTICALS“

The Board further reasoned in the denial of compliance with Art. 123 (2) EPC:

6.3 Interpreting the term "polypeptide of the invention" in this way leads however to the disclosure of combinations of selected features which were not directly and unambiguously disclosed in the patent application.

6.4 For instance, paragraph [0280] of the granted patent indicates that the invention also provides a fusion or chimeric protein which "comprises all or part (...) of a polypeptide of the invention operably linked to a heterologous polypeptide (i.e. a polypeptide other than the same polypeptide of the invention)". A skilled person reading this passage derives directly and unambiguously that a polypeptide of the invention or a part thereof may be comprised in a fusion or chimeric protein which is not the fusion protein of claim 6, as the polypeptide of the invention of said fusion protein is operably linked to a heterologous polypeptide. While it may not have been the intention of the drafters of the patent application, this interpretation is a direct consequence of the amendment of the description before grant of the patent.

(emphasis added)

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Thank you.

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