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**Datasheet for the decision
of 17 October 2024**

Case Number: T 1913/21 - 3.3.04

Application Number: 12723781.6

Publication Number: 2707383

IPC: C07K1/113, C12N5/00

Language of the proceedings: EN

Title of invention:

Methods of preventing and removing trisulfide bonds

Patent Proprietor:

Biogen MA Inc.

Opponents:

F.Hoffmann-La Roche AG
Maiwald GmbH

Headword:

Preventing trisulfide bonds/BIOGEN

Relevant legal provisions:

EPC Art. 54, 64(2), 112, 123(3)
EPC R. 116(2)
RPBA 2020 Art. 12(2), 12(3), 12(4), 21

Keyword:

Novelty - (no)

Category of granted claims

Second non-medical indication (no)

Auxiliary requests admissibly raised in opposition proceedings
(no)

Referral to the Enlarged Board of Appeal - (no)

Decisions cited:

T 0095/83, G 0002/88, G 0006/88, T 0892/94, T 0189/95,
T 0706/95, T 1049/99, T 0681/01, T 0062/02, T 0684/02,
T 1011/04, T 1343/04, T 1855/06, T 1179/07, T 0304/08,
T 2215/08, T 1039/09, T 1822/12, T 0151/13, T 2170/13,
T 0825/15, T 0308/17, T 1241/18, T 0364/20, T 1800/20,
T 0385/21, T 0023/22, T 0246/22, T 0446/22, T 0731/22,
T 2395/22

Catchword:

1. The rationale of the Enlarged Board of Appeal's decisions G 2/88 and G 6/88 is limited to claims directed to (new) non-medical uses of a known compound for a particular purpose, rather than to processes for production within the meaning of Article 64(2) EPC. In order to be a limiting technical feature of the claim, the (new) purpose must relate to the use rather than to a property of the product (see Reasons 15).

2. Claims which when correctly construed are directed to processes resulting in products referred to in Article 64(2) EPC are not subject to the special treatment established under G 2/88 and G 6/88, even if they contain the word "use" (see Reasons 9).

3. Where an invention relates to a new technical effect of a physical entity that can only occur as part of a process for the production or manufacture of a product, such that it is inextricably linked to and cannot occur in isolation from the production process, a claim directed to the "use" of the physical entity to achieve that effect must be regarded as directed to the production process *per se* (see Reasons 23).

4. For the criteria to be used in deciding whether auxiliary requests were admissibly raised in opposition proceedings, in the sense of Article 12(4) RPBA, see Reasons 38 to 52.



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Case Number: T 1913/21 - 3.3.04

D E C I S I O N
of Technical Board of Appeal 3.3.04
of 17 October 2024

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Decision under appeal: **Interlocutory decision of the Opposition
Division of the European Patent Office posted on
17 August 2021 concerning maintenance of the
European Patent No. 2707383 in amended form.**

Composition of the Board:

Chairwoman M. Pregetter
Members: A. Chakravarty
 A. Bacchin

Summary of Facts and Submissions

- I. In an interlocutory decision, the opposition division decided that the patent EP 2 707 383, as amended in the form of the main request and the invention to which it related, met the requirements of the EPC.
- II. The patent was opposed by two parties, opponents 1 and 2. Both opponents filed appeals against the opposition division's decision and are appellants I and II in the appeal proceedings. The patent proprietor is respondent to the appeals.
- III. In the decision under appeal, the opposition division considered and dismissed objections under Articles 54, 56, 83 and Article 123(2) and (3) EPC.
- IV. Both appellants submitted statements of grounds of appeal, to which the respondent duly replied. With its reply, the respondent maintained as its main request, that the appeals be dismissed and re-submitted sets of claims of auxiliary requests 1 to 7.
- V. Claim 1 of the set of claims held allowable by the opposition division (the main request) reads:

"1. Use of an inhibitor of cysteine degradation for reducing the formation of trisulfide bonds in proteins, wherein the inhibitor of cysteine degradation is selected from pyruvate, methyl pyruvate, ethyl pyruvate, glyceraldehyde, and glyoxylic acid; and wherein the use comprises: culturing cells expressing said proteins in the presence of an effective amount of the inhibitor of cysteine degradation, whereby trisulfide linkage formation in said proteins is

reduced relative to cells cultured in medium without the inhibitor of cysteine degradation."

Document numbering

VI. The following documents are referred to in this decision.

D3: WO 2008/141207

D24: WO 02/066603

VII. Oral proceedings were held as scheduled. During the oral proceedings the respondent withdrew all auxiliary requests other than auxiliary requests 4 and 5 and requested that the following questions, submitted in writing, be referred to the Enlarged Board of Appeal.

1. Should a claim to the use of a known compound for a particular purpose, which is based on a technical effect which is described in a patent and which has not previously been made available to the public, be interpreted as not including that technical effect as a functional technical feature, if the means of realization of the technical effect is further defined in the claim, and if so, is the claim open to an objection under Article 54(1)EPC ?

2. Does the answer to question 1 depend upon whether the means of realization defined in the claim relate to a process for producing a known product and/or whether the steps defining the means of realization relate to a process known in the art?

At the end of the oral proceedings, the chair announced the decision of the board.

VIII. The submissions of the parties, relevant to the decision, are summarised as follows.

Appellant II's submissions

Claim construction

IX. The opposition division's finding in the decision under appeal, that the claim did not merely relate to use of pyruvate for the production of proteins with a reduced amount of trisulfide bonds but was directed to the use of pyruvate for reducing trisulfide bond formation as a new property of pyruvate in cell culture had come as a surprise and was wrong. According to decision T 1855/06 "*The novelty of the use of the known compound for the known production of a known product cannot be deduced from a new property of the produced product. In such a case, the use of a compound for the production of a product has to be interpreted as a process for production of the product with the compound. It can be regarded as novel only if the process of production as such is novel*". The competent board in T 1855/06, held that this interpretation was in line with decisions G 2/88 and G 6/88 which concerned claims directed to the use of a known substance for a specific purpose. It explained that if a claim was for the use of a compound to make a product it had to be interpreted as a method of making the product by the compound, which could only be considered novel if the method of making as such had not been previously disclosed to the public.

In the case at hand, the purpose of claim 1 should be understood as that of protein production and not reducing the formation of trisulfide bonds, which is a mere technical effect of an old compound in an old use.

The respondent had argued that a novelty destroying document for the non-medical use of claim 1 had to disclose one of pyruvate, methyl pyruvate, ethyl pyruvate, glyceraldehyde, and glyoxylic acid used for obtaining the same effect and that none of the documents explicitly disclosed "reducing the formation of trisulfide bonds". However, "reducing the formation of trisulfide bonds" was actually a technical effect underlying the known non-medical purpose (production of proteins) of the (known) chemical compounds listed in claim 1. According to decision T 892/94 such subject-matter could not be novel.

A similar approach was taken in case T 23/22, where the board considered the feature "for controlling the sialic acid content" not to be a limiting feature and therefore came to the conclusion that claim 13 lacked novelty.

Novelty (Article 54 EPC)

Document D3 related to feed media that could be used for the production of recombinant proteins (see for example, under the heading "*Detailed description of the invention*" on page 5). It disclosed that pyruvate stabilised feed media containing tyrosine or cysteine (see examples). In Example 1, CHO cells were cultured in a cell culture medium and fed with feed medium A, which contained tyrosine, cysteine, and sodium pyruvate in varying concentrations (see page 30, lines 12-21 and Table 2). Accordingly, the CHO cells were cultured in the presence of an effective amount of an inhibitor of cysteine degradation, which, in this case, was sodium pyruvate and proteins were produced. In the decision under appeal, the opposition division considered that D3 did not disclose that pyruvate had an influence on

the level of H₂S. However, the opposition division was incorrect to look for such a property in any prior art document for the assessment of novelty, because claim 1 did not require the reduction of H₂S. As far as the purpose "for reducing the formation of trisulfide bond" was concerned, this was not a limiting feature of claim 1.

Document D24 related to methods and compositions for providing chemically defined media for growth of cultured mammalian cells for production of commercially useful amounts of expressed proteins (see "*Field of the invention*", page 1). The composition of the chemically defined medium shown in Tables A1-A3 and B1-B4 (see pages 14 to 19) contained 0.220 g/l sodium pyruvate and 0.003 g/l ascorbic acid (see Table A2 on page 16), as well as 5 mg/l linoleic acid (see Table A3 on page 17) and 1143.6 µg/l ferric citrate (see Table B2 on page 18). This medium was used to culture C463A cells (see, e.g. page 21, first two paragraphs).

The molar ratio of pyruvate to cysteine in the chemically defined medium was 3.99:1 (0.220 g/l sodium pyruvate corresponded to 9.5 mM sodium pyruvate and 0.4175 g/l L-cysteine HCl H₂O correspond to 2.38 mM L-cysteine HCl H₂O; see Table A2 on page 16 of document D24) which fell within the range of claim 6 of the MR.

As far as the purpose "for reducing the formation of trisulfide bonds" is concerned, this was not a limiting feature of claim 1.

Thus the subject-matter of claim 1 lacked novelty over the disclosure in both documents D3 and D24.

Referral of questions to the Enlarged Board of Appeal

There was no reason for a referral of questions to the Enlarged Board of Appeal. There was no basis to consider that the board had diverged from the teaching of G 2/88. In addition, question 1 appeared inconsistent with what was recited in the claim, as it distinguished between purpose and effect, whereas the claim treated the technical effect as the purpose. These questions had in any case already been answered by G 2/88.

Admittance of auxiliary requests 4 and 5

These auxiliary requests should not be admitted because they had not been substantiated, either in opposition or in appeal proceedings, although the respondent had had the opportunity to do so. Moreover the amendments made were not self-explanatory. The case law of the boards supported this approach, e.g. decisions T 750/18, T 1241/18 and T 1184/22, all dealt with similar situations.

Appellant I's submissions

- X. Appellant I made no objection of lack of novelty against the subject-matter of claim 1 of the main request. It did however support the referral of questions on deviation from G 2/88 to the Enlarged Board of Appeal. Whereas the proper formulation of questions was for the board to decide, a potential question was to ask whether, in case of a claim directed to the use of a product to achieve a new effect, novelty could be lost by additionally reciting process steps in the claim.

On the question of admittance of auxiliary requests 4 and 5, the position of appellant II was supported.

The Respondent's submissions

Main request - claim 1

Claim construction

- XI. The decision under appeal correctly held that the subject-matter of claim 1 of the main request was a second non-medical use and that "*The relevant decision[s] of the Boards of Appeal are G 2/88, T 279/93 and its further interpretation by T 892/94 and is discussed in the Caselaw, section I.C.8.1.3(e)*", such that the approach to claim interpretation adopted in e.g. G 2/88 should be applied in the present case. The opposition division was also right to state that "*a novelty anticipating document must disclose the use of the same substance in the same method for obtaining the same effect*" and that "*The underlying mechanism, whether being disclosed or not, whether being the same or another, is irrelevant*".

Consequently, the opposition division decided - correctly - that "*a document anticipating novelty must disclose the use of an ICD [inhibitor of cysteine degradation] during cell culturing for reducing trisulfide species of the desired protein... a document merely disclosing the presence of an ICD during cell culturing, but not relating the ICD to reduced trisulfide species cannot be considered to be novelty anticipating*".

On this basis the opposition division decided - again, correctly - that neither document D3 nor D24 deprived claim 1 of the main request of novelty.

Appellant II argued that the approach of G 2/88 and G 6/88 was not applicable to the present claims. Instead, claim 1 should be understood as relating to (any) use of pyruvate in protein production, regardless of whether or not such a use related to the reduced formation of trisulfide bonds. On this basis, claim 1 was said to lack novelty over documents D3 and D24.

However, appellant II's claim construction was wrong. In the case it cited (T 1855/06), the claims concerned the use of certain known compounds in a process of production of a product (elastane fibres). In the present case, the claims were not directed to the production of a product as such. Instead, the invention was concerned with reducing the formation of trisulfide bonds in proteins. Accordingly, the claims were directed to the use of an ICD selected from pyruvate, methyl pyruvate, ethyl pyruvate, glyceraldehyde, and glyoxylic acid for reducing the formation of trisulfide bonds in proteins. The use comprised culturing cells expressing said proteins in the presence of an effective amount of these compounds so as to reduce trisulfide linkage formation.

Put in terms of G 2/88, the invention concerned a new technical effect that led the skilled person to a new use, i.e. the use of such compounds to prevent trisulfide bond formation by inhibiting cysteine degradation.

Novelty (Article 54 EPC)

Documents D3 and D24 made no mention of the problem of trisulfide bond formation. They only disclosed components of cell culture media without providing any indication that the claimed compounds could be used to

prevent trisulfide bond formation. Thus, they did not directly and unambiguously disclose the use of an ICD selected from pyruvate, methyl pyruvate, ethyl pyruvate, glyceraldehyde and glyoxylic acid to reduce trisulfide bond formation in a method comprising culturing cells expressing proteins in the presence of an effective amount of the ICD. The opposition division had therefore been correct in holding that the subject-matter of claim 1 of the main request was novel over that disclosed in documents D3 and D24.

Referral of questions to the Enlarged Board of Appeal

If the board intended to deviate from the case law established by the Enlarged Board of Appeal in decisions G 2/88 and G 6/88 in its claim construction, the board was obliged under Article 21 RPBA to refer the question to the Enlarged Board of Appeal (see the text of the questions to be referred at point VII. above).

Admittance of auxiliary requests 4 and 5

These claim requests should be admitted as so-called carry-over requests. Auxiliary requests 4 and 5 had been admissibly raised and maintained in opposition proceedings in the sense of decisions T 364/20, T 1800/20 and T 246/22. Even if their substantiation was not extensive, the amendments were straightforward and the board and the other parties could clearly understand why the amendments overcame the objections of novelty and inventive step.

Furthermore, the claim requests should be admitted under Article 13(2) RPBA due to exceptional circumstances. These were that their admittance would simplify the proceedings since the amendments made

restricted the claims by introduction of features from dependent claims.

The parties' requests

XII. The appellants' (opponents 1 and 2) requests were as follows:

that the decision under appeal be set aside and that the patent be revoked in its entirety.

furthermore, that auxiliary requests 4 and 5, re-submitted by the patent proprietor with its reply to the statement of grounds of appeal, not be admitted into the appeal proceedings because of lack of substantiation.

XIII. The respondent's requests were as follows:

that the appeals be dismissed; alternatively

that the patent be maintained on the basis of the set of claims of auxiliary requests 4 and 5, re-submitted with the reply to the statements of grounds of appeals.

Reasons for the Decision

Main request - the patent as amended according to the main request considered by the opposition division in the decision under appeal

Introduction

1. The present invention relates to *"methods of preventing and eliminating the formation of trisulfide bonds in proteins during protein production"* (paragraph [0001] of the patent). According to paragraph [0006] of the patent *"removal of [unwanted] trisulfide bonds by exposure to cysteine in solution [as done previously] has several drawbacks, in particular for large scale processing. For example, large quantities of cysteine are required. This method also necessitates a separate step to remove cysteine from the sample after trisulfide bonds are removed. In addition, removal of trisulfide bonds by exposure to cysteine in solution can promote aggregation through the formation of undesirable disulfide linkages. Therefore, in order to address the limitations of previous methods for reducing trisulfide bonds, the methods described [...] provide efficient and improved means for preventing and eliminating the formation of trisulfide bonds in proteins (such as, for example, in antibodies) during production and purification procedures used in the manufacture of such proteins"*.

Novelty (Article 54 EPC)

Claim construction

2. Claim 1 is for the "Use of an inhibitor of cysteine degradation for reducing the formation of trisulfide bonds in proteins...". "An inhibitor of cysteine degradation" is a chemical compound, i.e. a physical entity, while "for reducing the formation of trisulfide bonds in proteins" is an effect. The claimed use further comprises certain method steps of cell culturing (see below point 18.).
3. The parties disagree about whether the stated effect of "reducing the formation of trisulfide bonds in proteins" is a functional technical feature, limiting the claimed use or not. In the decision under appeal, the opposition division took the view that the claim was formulated as a second non-medical use claim, namely as the use of a known compound for a particular purpose, which is based on a technical effect. In its view the claim was therefore subject to the rationale of decisions **G 2/88** and **G 6/88** of the Enlarged Board of Appeal (see in particular points 42 and 50 of the reasons of the decision under appeal).
4. In the present case, claim construction plays a key role in deciding on the novelty of the claimed subject-matter (see decisions G 2/88, Reasons 6 and G 6/88, Reasons 8, which confirm the first step in the assessment of novelty to be a proper construction of the claim in order to determine its technical features, and points 20 to 22 of the board's communication pursuant to Article 15(1) RPBA).

5. When construing a claim in a patent, the claimed subject-matter is determined by applying the established principles of claim construction, i.e. giving the terms used in a claim their ordinary meaning in the context of the claim in which they appear (see **T 681/01**, reasons 2.1.1). This principle also applies when determining what "category" a claim is in, e.g. whether it is directed to a product or process.

6. These principles of claim construction were also applied in decisions G 2/88 (OJ EPO 1990, 93), in which the Enlarged Board had to decide whether a change of claim category by means of amendment gave rise to an extension of the scope of protection, in violation of Article 123(3) EPC, and in G 6/88 (OJ EPO 1990, 114). In relation to this, the Enlarged Board established that *"a claim to the use of a known compound for a particular purpose, which is based on a technical effect which is described in the patent, should be interpreted as including that technical effect as a functional technical feature, and is accordingly not open to objection under Article 54(1) EPC provided that such technical feature has not previously been made available to the public"* (see G 2/88, Headnote III and G 6/88, Headnote). In other words, where a claimed invention involves a new technical effect of a known compound and the claimed subject-matter is the use of that known compound to achieve the new purpose based on the new effect, the subject-matter is novel even if the physical activity (the means of realisation) is identical to a physical activity known in the art (see G 2/88, Reasons 9.1).

7. It is important to note however that in decision G 2/88, the Enlarged Board, as part of its considerations relating to Article 123(3) EPC (see

point 5.1 of the Reasons), also made a distinction between categories of claims, namely between a use of a physical entity for achieving an effect on the one hand and a process for the production of a product on the other. The Enlarged Board emphasised that a claim directed to the use of a known compound for a particular purpose is not a process claim within the meaning of Article 64(2) EPC. While a process claim extends its protection to "the product directly obtained by such process" by virtue of Article 64(2) EPC, a "use" claim of the type considered by the Enlarged Board does not result in a product and therefore no protection under Article 64(2) EPC arises. For this reason the Enlarged Board found that the change of category from a product claim to a use claim does not normally extend the scope of protection and is not in violation of Article 123(3) EPC. However an extension of scope is not excluded with a change into a process claim. In this context it stated that *"...it could be considered that such a "use" claim is notionally equivalent to a claim to a "process including the step of using the compound", and that the effect of Article 64(2) EPC is to extend protection to the "product" of such process (whatever it is); thus there would be extension of protection within the meaning of Article 123(3) EPC by reason of the change from a claim to one physical entity (the compound) to a different physical entity (the "product" of the process of using the compound). In the Board's view, in relation to such a change of category to a "use" claim, Article 64(2) EPC does not normally have such an effect, however, for the following reason. Article 64(2) EPC is not directed to a patent whose claimed subject-matter is the use of a process to achieve an effect (this being the normal subject of a use claim): it is directed to a European patent whose*

*claimed technical subject-matter is a **process of manufacture of a product**; the Article provides that for such a patent, protection is conferred not only upon the claimed process of manufacture, but also upon the product resulting directly from the manufacture.*

Thus, provided that a use claim in reality defines the use of a particular physical entity to achieve an "effect", and does not define such a use to produce a "product", the use claim is not a process claim within the meaning of Article 64(2) EPC (emphasis added by the present board).

8. It is apparent from this that the Enlarged Board's findings relating to new uses of known compounds are limited to uses/methods/processes which are not processes resulting in products, as referred to in Article 64(2) EPC.
9. It is further apparent that claims which when correctly construed are directed to processes resulting in products referred to in Article 64(2) EPC are not subject to the special treatment established under G 2/88 and G 6/88, even if they contain the word "use".
10. This strict distinction between claims directed to a use of a known compound for achieving an effect, which does not result in a product and claims directed to a process leading to the production of a product, made by the Enlarged Board in G 2/88 and G 6/88 has been implemented consistently in a number of subsequent decisions reflecting that teaching, some of which also cited by the appellants. In these decisions it was repeatedly pointed out that the criteria of G 2/88 and G 6/88 are to be interpreted narrowly and are not transferable to claims directed to a method of

production/manufacture, even if the claim recites a purpose or an effect.

- 10.1 In **T 304/08** (Reasons 3.3.2) in which the claim concerned a method for reducing malodour associated with a disposable absorbent product and comprising production steps, the Board confirmed that the criteria set out in G 2/88 and G 6/88 "*may only be applied to claims directed **exclusively** to the use of a substance for achieving an effect. They cannot be extended to interpreting a claim to a method for producing a product, which includes one or more physical steps, wherein the purpose of carrying out said method is defined, as including said purpose as a functional technical feature*" (emphasis by the board). The Board thus interpreted the claim as a process claim for the production of a product, namely an absorbent treated with a surface-active agent, and construed the process as *suitable* for reducing malodour. The indication of the intended purpose of the method could at the most be seen as limiting to the extent that the method had to be *suitable for that use*. In other words, disclosure of the same method without an indication of the particular purpose, although the method was nevertheless suitable for it, would have anticipated a claim to the method for that particular purpose (see **T 304/08**, Reasons 3.3.4).

An identical statement is also found in **T 1039/09** (Reasons 18) in which the underlying claim was directed to a (known) method for a particular purpose (producing a product) and included method steps.

- 10.2 In **T 1179/07** (Reasons 2.1.3) it was stated that the decisive findings in G 2/88 and G 6/88 concerned a claim to the use of a compound for a previously unknown

purpose. The cited decisions of the Enlarged Board were however silent on the issue of whether the purpose could be considered a functional technical feature of a claim directed to a process for producing a product characterised by process steps. Although the "use of a compound" could be regarded as a process including the compound use as a process step, a use claim could not normally be treated as equivalent to a process claim because Article 64(2) EPC was not, as a rule, applicable to use claims.

The competent board also noted that despite the indicated purpose, the process claimed was *de facto* a classical process for the manufacture of a product. Were the board to extend the findings made in G 2/88 and G 6/88 to the granted process claim, this would confer once again protection under Article 64(2) EPC to the product resulting from granted process claim 1, even though that product was already known in the prior art and obtained by precisely the same process as that described in the prior art. It could not, however, be in keeping with the object and purpose of Article 64(2) EPC to extend its protection to a product obtained by a known process. The board found that precisely this difference in the treatment of process and use claims in the context of Article 64(2) EPC, left no room to extend the rationale of G 2/88 and G 6/88 with regard to the use of a known compound for a previously unknown purpose to process claims. As a consequence, the purpose indicated in the process claim could not confer novelty.

10.3 The distinction, in the context of G 2/88 and G 6/88, between claims directed to the use of a physical entity for achieving an effect and claims directed to a use of a process was also emphasised in **T 684/02** (Reasons

5.4). In that case, the claim was directed to the use of a process for achieving an effect, where the process resulted in the production of an improved product, subject to the extension of protection under Article 64(2) EPC. The competent board concluded that "*The Enlarged Board of Appeal limited its Orders in G 0002/88 (part (iii)) and in G 0006/88 explicitly to a claim to the "use of a known compound", in which a technical effect should be interpreted as a functional technical feature. In the Board's view, this leaves no room for further expansion of this ruling to claims worded otherwise (Nos. 5.3.4 and 5.3.5 of the reasons)*" (Catchword 1.).

10.4 Similar findings were reached, *inter alia*, in **T 825/15** (Reasons 13), **T 2170/13** (Reasons 4.2 to 4.5), **T 1822/12** (Reasons 3.1.2 to 3.1.4), **T 2215/08** (Reasons 2.4.1), **T 1343/04** (Reasons 2) and **T 1049/99** (Reasons 8.4.4 and 8.5).

11. The board also shares appellant II's view that the findings of decision **T 1855/06** are applicable to the present case, in particular as regards the appropriate claim construction. In that case the board highlighted the fact that "*If an alleged new use undoubtedly concerns a non-medical use, **the novelty of the use of a known compound for the known manufacture of a known product cannot be derived from a new property of the product produced.** In such a case, the use of a compound in the manufacture of a product is to be interpreted as a process of manufacture of the product using the compound and it can only be considered novel if the process of manufacture as such has not previously been made available to the public. In order to comply with G 2/88 and G 6/88, the claimed use would then have to relate to **a new way of exploiting the newly recognised***

property, and not merely to the manufacture of a product possessing that property" (see Catchword 1 and Reasons 5.3; emphasis and translation into English by the present board).

- 11.1 It further held that where the stated purpose was improving an already known property of the product to be produced, the use could not be regarded as a new technical activity within the meaning of G 2/88 and G 6/88 (see Catchword 2 and Reasons 6).
- 11.2 The present board does not agree with the respondent that the findings of T 1855/06 do not apply to the present case because, in its view, the claims considered in T 1855/06 concern the use of particular known compounds in a process of production of a product (elastane fibres) whereas the present claim is not directed to the production of a product as such.
- 11.3 In fact, the question of whether the present claim relates to a process for the production of a product or not must be settled by analysis of the wording of the claim itself, as was the case in T 1855/06. Moreover, the finding in T 1855/06 that the properties of the product were known, was taken in the context of novelty, and does not affect the general statements made in T 1855/06 with regard to claim construction. These logically precede the novelty assessment and are fully applicable to the present case. Thus the clarification set out in T 1855/06 that for the rationale of G 2/88 to apply, the limiting technical feature must relate to the use and not to a property of the product, also applies to the present case.
12. The same is true in relation to the respondent's argument (made at the oral proceedings) that the

findings in **T 23/22** do not apply to the present case because in that case the board found that the claimed use of a certain compound as additive in a medium for eukaryotic cells was previously known. This finding, in the context of novelty, is distinct from the preceding step of claim construction by the board, in which it correctly pointed out that in a claim drafted with nested purposes, the question arises as to which of the purposes is a limiting feature of the claimed use (Reasons 2). Thus, the board identified the purpose of the use of the compound as the limiting feature of the claim, i.e. the use as additive in a medium for eukaryotic cells; whereas the effect of the use, i.e. for controlling the sialic acid content of a glycoprotein produced by a eukaryotic cell, which actually constitutes a property of the product, was not construed as limiting the claim (see also Reasons 38 in the context of sufficiency).

13. The board also concurs with the findings in **T 892/94**, which has been relied on by appellant II. In that case, in which the relevant claim related to the use of aromatic esters as an inhibitor of esterase producing micro-organisms, the board explained that a newly discovered technical effect in the context of the use of a known substance for a known non-medical purpose cannot confer novelty, if the newly discovered technical effect already underlay the known use of the known substance. To confer novelty it would be required that the newly discovered effect did result in either a new technical application or a new use of the known substance (Reasons 3.4 of the decision).

- 13.1 This view was confirmed and further expanded on in a series of later decisions, that hold that a new property of a substance, i.e. a new technical effect,

does not necessarily give rise to a new use for that substance; rather the property might merely explain the mechanism behind the use already described in the prior art (see **T 189/95**, Reasons 2.4 and **T 151/13**, Reasons 4.4); or that the discovery that the same known means led to an additional effect when they are used for the same known purpose (i.e. known use) cannot confer novelty on this known use (see **T 706/95**, Reasons 2.5).

14. The respondent relied on decisions **T 62/02** and **T 1011/04**, in which the claims, in the format of the use of a compound to achieve a particular effect and including method steps, closely corresponded to present claim 1. In those cases the board interpreted the claim in the sense of G 2/88 as allowing the intended technical effect to be considered a technical feature of the claim (see T 62/02, Reasons 2.1 and 3.4)
- 14.1 The present board notes that the findings in those decisions do not reflect the prevalent established jurisprudence, as summarised above, in particular with regard to the fact that the effect recited in the claim must relate to the use, rather than to the product directly obtained by the process steps within the meaning of Article 64(2) EPC, in order to constitute a limiting feature in the sense of G 2/88. Most importantly these decisions do not provide any reasoning as to why the claims were not regarded as claims directed to a process for the manufacture of a product, which would not allow the principles of G 2/88 to be applied, or conversely whether the competent boards were of the view that the principles of G 2/88 are transferable to process claims and why this should be so.

15. From the above analysis it can be concluded that there is a consistent line of jurisprudence, holding that the rationale of the Enlarged Board of Appeal's decisions G 2/88 and G 6/88 is limited to claims directed to (new) non-medical uses of a known compound for a particular purpose, and does not apply to processes for production within the meaning of Article 64(2) EPC. Furthermore, in order to be a limiting technical feature of the claim, the new purpose must relate to the use rather than to a property of the product. Thus, in the case of processes for producing a product, the "aim" of the process is not a functional feature of the claimed subject-matter even if it is explicitly recited in the claim. Novelty of the claimed subject-matter is assessed solely on the basis of the remaining features of the claimed process.
16. The present claim is directed to a "use" and its subject-matter is therefore a physical activity as referred to by the Enlarged Board of Appeal in decision G 2/88 (see Reasons 2.2). There was no dispute on this issue.
17. In view of the above considerations, the board must determine whether or not the "use" of claim 1 is in fact a process to produce a product or if it is a use to achieve a (new) technical effect.

The claim

18. Claim 1 has five parts:
- i) Use of an inhibitor of cysteine degradation
 - ii) for reducing the formation of trisulfide bonds in proteins,

iii) wherein the inhibitor of cysteine degradation is selected from pyruvate, methyl pyruvate, ethyl pyruvate, glyceraldehyde, and glyoxylic acid;

iv) and wherein the use comprises: culturing cells expressing said proteins in the presence of an effective amount of the inhibitor of cysteine degradation,

v) whereby trisulfide linkage formation in said proteins is reduced relative to cells cultured in medium without the inhibitor of cysteine degradation.

Parts i) and iii) define the compound used. Parts ii) and v) define the aim or purpose of the use and part iv) defines a process or method (a physical activity) in terms of steps to be carried out to achieve the aim.

From part iv) of the claim it is clear that the claimed "use" comprises the physical activity of carrying out the defined process steps, i.e. culturing cells expressing said proteins in the presence of an effective amount of the inhibitor of cysteine degradation. It is further apparent that carrying out these steps leads directly to the production of proteins having a reduced number of trisulfide linkages relative to proteins from cells cultured in a medium without the inhibitor of cysteine degradation.

19. In the board's view, claim construction must be done on the basis of the technical features of the given claim and should not be unduly influenced by the format of the claim (see also point 5. above). As stated in the above cited jurisprudence and emphasised in **T 308/17** *"it is irrelevant whether the claim refers to a 'method' or a 'use', as both these words describe a*

physical activity. In order to determine what the subject-matter claimed is, it is necessary to consider the particular wording of the claim" (see Reasons 30).

20. Thus, the claimed subject-matter comprises carrying out process steps, which result in the production of a product. Following the principles laid down in G 2/88 and G 6/88 and the jurisprudence implementing them, indicated above, in such circumstances, the claimed subject-matter must be regarded as a process for the production of proteins with a "reduced" number of trisulfide linkages, regardless of the fact that the claim is drafted as the "use" of a chemical compound. Indeed, the technical effect stated in part ii) of the claim of "reducing the formation of trisulfide bonds in proteins", cannot occur except as part of a process for the production or manufacture of proteins and as such is inextricably linked to the production process.

21. The board considers that the proteins produced by the claimed process would be covered by Article 64(2) EPC as "products directly obtained" by the claimed process. The board concurs in this regard with the findings in T 892/94 (Reasons 3.8) that applying the concept of novelty developed in G 2/88 to claims for processes of producing a product, even when drafted as use for achieving a technical effect that results in an improved product could potentially result in a permanent monopoly of the use of a known substance for a known purpose. Such a permanent monopoly would arise from the repeated drafting of claims for a process of production including a new, possibly only subtly different, technical effect associated with this known process (see also T 1179/07 cited above, Reasons 2.1.3).

22. In the present case (and as was the case for claim 1 of auxiliary requests XI and XII in T 308/17), the choice of drafting the claim as a "use" of chemical compound cannot mask the fact that the claim defines a production process and the new technical effect can only take place in the context of this process. The mere formatting of the claim to give the appearance that its subject-matter falls under the principles established by G 2/88 cannot circumvent the fact that on analysis, the claim is directed to a use or process for the production of a product, here one having the 'improved' property of having 'fewer' trisulfide bonds.
23. Thus the new technical effect recited in the claim of reducing the formation of trisulfide bonds in proteins pertains to the product (the protein produced) and cannot be considered a technical limiting feature of the "use" according to G 2/88. Indeed, where an invention relates to a new technical effect of a physical entity that can only occur as part of a process for the production or manufacture of a product, such that this effect is inextricably linked to and cannot occur in isolation from the production process, a claim directed to that "use" of the physical entity to achieve that effect must be regarded as directed to the production process *per se*.
24. This is analogous to the case when an invention relates to a second medical use (i.e. claims drafted under Article 54(5) EPC) where the discovery of a previously unknown property of a compound (i.e. the substance or composition according to Article 54(5) EPC) underlies the known effect. In such a case, the mere explanation of an effect obtained when using a known compound cannot confer novelty on a known use in a method (i.e. a process), even if the explanation relates to a

pharmaceutical effect which was not known to be due to that compound (see Case Law of the Boards of Appeal of the European Patent Office, 10th edition 2022, I.C. 7.2.4.i) "*Discovery of a previously unknown property of a compound underlying the known effect*", analogous to I.C.8.1.3.e)).

25. The assessment of novelty in the present case will therefore be done by answering the question of whether or not there was a disclosure forming part of the state of the art of a process having the same physical steps (culturing cells expressing said proteins in the presence of an effective amount of a compound that may act as an inhibitor of cysteine degradation) and leading to the production of the product defined in the claim.

Novelty over documents D3 and D24

26. An objection of lack of novelty with regard to document D3 was dismissed by the opposition division in the decision under appeal because it "*does not disclose that pyruvate has an influence on the level of H₂S and trisulfide formation. The stabilisation of cell media and the prevention of cystine precipitation by cysteine stabilisation are not the same purpose*" (see point 46 of the decision under appeal).
27. As was noted by the opposition division, D3 discloses "*stable feed media containing pyruvate, methods for stabilizing feed media comprising adding pyruvate to a medium, methods for using stable feed media, and proteins produced by cultures fed with a medium of the invention*" (see page 2, "Summary of the Invention"). In Example 1, a CHO cell line producing a recombinant protein was cultured in a commercially available base

medium and fed with feed medium A which contained tyrosine, cysteine and sodium pyruvate in varying concentrations (see page 30, lines 12 to 21 and Table 2 of document D3). The concentration of pyruvate in the feed medium is disclosed as being in the range from 0.9 mM to about 40 mM (see page 10, lines 32 to 34). Accordingly, D3 discloses a process for the production of a recombinant protein in which CHO cells are cultured in the presence of sodium pyruvate.

28. Similarly, in the decision under appeal, document D24 was held not to "*disclose that pyruvate could have an influence on trisulfide formation. Trisulfide compounds are not mentioned in D24.*"
29. D24 discloses chemically defined media and their use as culture media in the production of recombinant proteins (see page 2, "Summary of the Invention" and page 3, "Detailed Description"). The media disclosed in table A2 (see pages 15 and 16) contains sodium pyruvate at a concentration of 0.220 grams per litre. Example 1 discloses the use of pyruvate containing media to culture a myeloma cell line for the production of IgG.
30. In arguing for lack of novelty, appellant II submitted that documents D3 and D24 disclose processes for the production of recombinant proteins comprising culturing cells expressing said proteins in the presence of pyruvate. In its view the physical steps of the methods disclosed in these documents are identical to the steps recited in the claim, meaning the claimed subject-matter lacks novelty. The aim stated in the claim (reducing the formation of trisulphide bonds compared to the amount of trisulphide bonds in proteins cultured in medium without the pyruvate) was not a feature of the claimed subject-matter.

31. The respondent's main line of argument in favour of novelty was based on its construction of the claim as pertaining to a non-medical use for achieving an effect falling under the principle established by G 2/88. It submitted that neither document D3 nor D24 even mentioned the stated effect, i.e. the reduction of the formation of trisulfide bonds in proteins, the avoidance of which was a feature of the claim. In its view, these documents only disclosed components of cell culture media without providing any indication that the claimed compounds could be used to prevent trisulfide bond formation and therefore they did not directly and unambiguously disclose the use of pyruvate to reduce trisulfide bond formation in a method comprising culturing cells expressing proteins in the presence of an effective amount of the pyruvate (the ICD).
32. The respondent's argument cannot succeed because the board does not agree with its construction of the claim (see points 23. and 25. above). In view of the board's claim construction, the reduction of the formation of trisulfide bonds in proteins is not a feature of the claimed subject-matter to be taken into account for assessing novelty. As can be taken from points 26. to 29. above, documents D3 and D25 both disclose methods comprising culturing cells expressing said proteins in the presence of pyruvate (a compound defined in the paragraph [0042] of the patent as an inhibitor of cysteine degradation). In view of the above considerations on claim construction, the subject-matter of claim 1 lacks novelty over the disclosure in documents D3 and D24.
33. The present decision is in line with recent decision **T 385/21** which dealt with a claim was directed to "*a method of controlling quality and quantity of*

posttranslational modification of a recombinantly produced polypeptide/protein (glycoprotein)" comprising the physical steps

a) cultivating the eukaryotic cells in a suitable medium under conditions which allow the expression of the polypeptide/protein, wherein the content of the dissolved CO₂ (pCO₂) in the medium is at a first value during the initial growth phase of the eukaryotic cells, allowing the eukaryotic cells to grow, and

b) increasing or decreasing the content of the dissolved CO₂ (pCO₂) in the medium during the production phase of the eukaryotic cells to a second value.

34. As in the present case, the claim recited an aim which was not the production of a product but was the avoidance of unwanted by-products during cell culture for producing recombinant protein. That case too involved a purported new effect of a compound added to a culture medium. The competent board held that *"claim 1, which recites only steps of production, does indeed define a method of production, and that the purpose of controlling quality and quantity of posttranslational modifications is not a limiting feature of the method"*. The claimed subject-matter was held to lack novelty over a disclosure in the state of the art of a method having the same physical steps but where the stated aim was not disclosed (see Reasons 2 to 5.4 and 10 to 12).

35. Similar considerations in relation to a purported new effect were made in decision T 23/22, where the effect related to a property of the product, see point 12., above.

36. Thus, adopting either the approach used in decision T 385/21 or in T 23/22 would lead to the (same) conclusion of lack of novelty over the disclosure in D3 and D24.

Auxiliary requests 4 and 5 (re-submitted with the reply to the statements of grounds of appeals)

Admittance

37. Auxiliary requests 4 and 5 were filed during the proceedings before the opposition division but were not dealt with because a higher ranking request was held allowable. They were re-filed with the statement of grounds of appeal.
38. Since the object of appeal proceedings is the decision under appeal (Article 12(2) RPBA), auxiliary requests submitted during the opposition proceedings but not decided upon, not even as regards their admittance, do not automatically form part of the appeal proceedings.
39. If such auxiliary requests are re-filed in appeal, they are regarded as an amendment, unless the patent proprietor demonstrates that they were admissibly raised and maintained in the proceedings leading to the decision under appeal. Otherwise they may be admitted into the proceedings only at the discretion of the board (Article 12(4) RPBA).
40. At the oral proceedings, the respondent submitted that auxiliary requests 4 and 5 should be admitted into the proceedings because they had been admissibly raised and maintained in the opposition proceeding. The respondent referred to three different approaches outlined in the jurisprudence of the Boards of Appeal with regard to

the interpretation of the requirement *admissibility raised and maintained*, and referred *inter alia* to decisions **T 364/20**, **T 1800/20** and **T 246/22**, and submitted that auxiliary requests 4 and 5 were admissible under any of these approaches.

41. It is not necessary to go into the details of the different approaches set out in the above mentioned decisions, because the board finds that auxiliary requests 4 and 5 are not admissible because they do not meet at least a common requirement in these decisions, namely that an explanation is given as to why the amendments have been made and how they are intended to overcome the objections raised. Although this aspect is not discussed in T 1800/20 as such, due to the underlying factual situation, the decision does mention the suitability of the submission to overcome the objections raised (see Reasons 3.4 b)). The board however, is not convinced that the criteria found crucial in that decision, which are adapted from those used in deciding on admittance in appeal proceedings, are applicable to the present circumstances, as further explained below (point 43.).
42. The present board agrees with the considerations in decisions T 364/20, T 1800/20 and T 246/22, that no guidance is given in the RPBA or in their explanatory remarks (contained in the Supplementary publication 2, OJ EPO 2020, 17), as to the exact meaning of "admissibly raised".
43. However, the board finds that the wording of Article 12(4) RPBA by reference to "the proceedings leading to the decision under appeal" should be construed in the present case with regard to opposition proceedings and the criteria applicable to them. In practice, this

requires an assessment of whether the opposition division had discretion not to admit a request, and how that discretion should have been exercised in the circumstances if a decision on admittance had been required. This approach was also adopted in other decisions, either explicitly (see e.g. T 364/20, Reasons 7, **T 2395/22**, Reasons 1.3.3) or implicitly (**T 446/22**, Reasons 3.4 and **T 731/22**, Reasons 2.2). It would be inappropriate and unfair (in this case) to the patent proprietor, if the board applied the criteria in Article 12(4), third sentence, RPBA which are intended to guide the exercise of discretion on admittance of auxiliary requests filed in appeal, as it would apply unduly strict requirements. These criteria are proper of the appeal proceedings and could not have been considered by the patent proprietor at the time of filing the auxiliary requests. For this reason a reference to the relevant EPC provisions and to the Guidelines for examination *applicable at the time when the auxiliary requests were filed*, i.e. the version applicable at the time of the facts, is appropriate, since they contain the criteria that an opposition division would apply (see Part E-III, 8.6, Part E-VI, 2.1 and 2.2; Part H-II, 3, in particular 3.5 and Part H-III, 3 and subsequent sections of the Guidelines for examination in the March 2021 version). In addition, the Guidelines for examination reflect the consolidated jurisprudence of the Boards of Appeal on the criteria for admittance of requests to be applied in opposition proceedings.

44. The mere fact that auxiliary requests are filed late is not *per se* a reason for not admitting them. A principle consolidated in the jurisprudence of the boards of appeal (see e.g. **T 95/83**, Reasons 8), adopted in the first instance and consistently reflected in the

Guidelines for examination (see also Part H-II, 2.7 and Part E-III, 8.6, in the March 2021 version), is that auxiliary requests are not inadmissible filed simply because they were filed after a period or date specified (e.g. the date specified under Rule 116(1) and (2) EPC), but only if in addition they are filed *without proper justification*. A proper justification is normally considered to be present when the subject of the proceedings has changed, e.g. because of a changed opinion of the opposition division (see also E-III, 8.6), or due to a new document or a new objection submitted/raised by the opponent(s)/the opposition division. Auxiliary requests filed after the period or date specified and absent a proper justification are considered "late" and their admittance is subject to the discretion of the opposition division, which would be empowered to rely on criteria such as the clear allowability of the request (see Guidelines for examination, March 2021, H-II, 2.7.1, applicable to late requests filed in opposition, see last sentence of the section).

45. With regard to the present case, auxiliary request 4 was filed in opposition as auxiliary request 14 on 30 April 2020, *within* the date specified under Rule 116(2) EPC given with a first communication of the opposition division in preparation of the oral proceedings.

45.1 Auxiliary request 5 was filed in opposition as auxiliary request 15 on 24 May 2021, and thus *after* the date specified under Rule 116(2) EPC (expiring on 23 April 2021) given with a second communication of the opposition division in preparation of the oral proceedings. The board finds that, despite not being filed within the date specified, this latter auxiliary

request was filed with justification, as it was submitted in direct reaction to new objections under Articles 123(2) and 84 EPC raised by opponent 2 within the date specified under Rule 116(1) EPC. Therefore, since it was a legitimate reaction of the patent proprietor to a change in the subject of the proceedings, the filing of auxiliary request 5 cannot be considered as inadmissible.

46. The Guidelines for examination further contain a requirement similar to the one of substantiation in the RPBA (Article 12(3) and 12(4), fourth sentence), namely that an explanation must be provided as to why the amendments have been made and how they are intended to overcome the objections raised (Guidelines for examination, March 2021, see H-II, 2.7.1, applicable to late requests filed in opposition, see last sentence of the section).
47. In this respect, the appellants objected to the admittance of these auxiliary requests for "lack of substantiation" both in opposition and in appeal proceedings and because the amendments were not self-explanatory.
48. The board accepts the respondent's arguments that neither the EPC nor the RPBA define the amount of substantiation required when filing auxiliary requests. This clearly depends on the circumstances of the case, such as the kind and the extent of the objections raised by the opponent(s) or by the opposition division/the board, the stage of the proceedings at which the auxiliary requests are filed and even the fact whether they are filed in opposition or in appeal proceedings.

49. Furthermore, when amended sets of claims, first filed in opposition but not decided upon, are maintained in appeal proceedings, the patent proprietor has to demonstrate that they were *admissibly raised and maintained in the proceedings leading to the decision under appeal* (Article 12(4), first sentence RPBA). In appeal proceedings this burden is on the patent proprietor, and the board cannot be expected to investigate if and when, in the course of the opposition proceedings, an explanation was provided why the amendments were made and how they were intended to overcome the objections raised.
50. With regard to the present case, when filing auxiliary requests 4 and 5 in opposition proceedings, as auxiliary requests 14 and 15, the respondent merely submitted that the amendments introduced further limited the scope of the granted claims and therefore further distinguished the claimed subject-matter from the prior art. With particular regard to auxiliary requests 4 and 5 they all included the additional limitation of granted claim 14, that the protein is an antibody or Fc-fusion protein. No reason was submitted as to why the new features introduced to claim 1 would overcome the objections raised, at least by conferring novelty in view of documents D3 and D24, in a straightforward manner.
51. This fact is sufficient to conclude that having regard to the stage of the proceedings in which these requests were filed in opposition, the justification for their filing at that stage and the explanations of how they are intended to overcome the objections raised (see point 46. above, and Guidelines for examination, March 2021, H-II, 2.7.1, last sentence of the section), auxiliary requests 4 and 5 would not have been admitted

in the opposition proceedings, had a decision on their admittance been required. They were thus not admissibly raised in the proceedings leading to the decision under appeal and therefore constitute an amendment within the meaning of Article 12(4) RPBA, the admittance of which is subject to the discretion of the board.

52. In appeal the respondent only provided a statement of where a basis for the amendments could be found in the application as filed and the statement that "*These requests improve the Patentee's position because they limit the claim scope and therefore further distinguish the claims from the disclosure in the prior art. They therefore address the objections raised at first instance by the Opponents*". This cannot be regarded as a full substantiation in the sense of Article 12 (3) and (4), fourth sentence, RPBA. No reasons have been provided as to how the amendments overcome at least the novelty objection, nor these reasons are self-explanatory (see Case Law of the Boards of Appeal of the European Patent Office, 10th edition 2022, V.A. 5.12.6, see also e.g. **T 1241/18**, Reasons 3).
53. In a further line of argumentation on admittance, the respondent submitted that auxiliary requests 4 and 5 should be admitted under Article 13(2) RPBA. Exceptional circumstances would be given by the resulting simplification of the proceedings due to amendments which further restricted the claims by introduction of features from dependent claims.
54. Due to the lack of any substantiation of these auxiliary requests and particularly the fact that it is not straightforward how the amendments can overcome the objections raised, the board fails to see how the

proceedings could be simplified through these amendments.

55. In view of this, the board decided not to admit the claim requests into the proceedings.

Request for a referral of questions to the Enlarged Board of Appeal (Article 112 EPC)

56. The respondent's request to refer questions of law to the Enlarged Board of Appeal pursuant to Article 21 RPBA is based on its understanding that the board's conclusion on claim construction and novelty meant that the board had deviated from the earlier decision of the Enlarged Board of Appeal G 2/88 (see section VII. above). Had the board followed the teaching in G 2/88, the technical effect of reducing trisulfide bond formation in proteins could not have been ignored for the purpose of claim construction and the assessment of novelty. Moreover, Article 21 RPBA was a mandatory provision and the board had no discretion to ignore the obligation to refer questions to the Enlarged Board should it deem it necessary to depart from an earlier interpretation of the Convention given by the Enlarged Board.

57. However, as extensively explained in points 6. to 15. above, the teaching of G 2/88 is limited to specific claimed subject-matter, which upon a correct claim construction, is not present in this case. Clear explanations were given both in G 2/88 and in the subsequent jurisprudence as to why the subject-matter claimed in the present case could not fall under its rationale. The present board has therefore not deviated from this jurisprudence and consequently the

respondent's request for a referral of questions to the Enlarged Board of Appeal was rejected.

58. Since no claim request is allowable, the decision under appeal must be set aside and the patent revoked.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The patent is revoked.

The Registrar:

The Chairwoman:



A. Vottner

M. Pregetter

Decision electronically authenticated