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**Datasheet for the decision  
of 26 September 2019**

**Case Number:** T 1695/18 - 3.3.01

**Application Number:** 09797440.6

**Publication Number:** 2300008

**IPC:** A61K31/47, A61P13/00

**Language of the proceedings:** EN

**Title of invention:**

SUPPLEMENTATION OF PROPANE-1,2,3-TRIOL AND WATER IN FASTING  
SUBJECTS

**Patent Proprietor:**

Lück, Stephan

**Opponent:**

DrSlym Vital GmbH

**Headword:**

Hypoglycaemia/LÜCK

**Relevant legal provisions:**

EPC Art. 53(c), 100(a), 54  
RPBA Art. 12(4), 13

**Keyword:**

Transfer of opponent status (yes)

Novelty - main request and auxiliary requests 1 to 7 (no) -  
non-limiting, non-therapeutic use

Admission of late filed requests - auxiliary requests 16 to 23  
(no)

**Decisions cited:**

G 0001/83, G 0005/83, G 0006/83, G 0007/93



**Beschwerdekammern**

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Case Number: T 1695/18 - 3.3.01

**D E C I S I O N**  
**of Technical Board of Appeal 3.3.01**  
**of 26 September 2019**

**Appellant:** Lück, Stephan  
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**Decision under appeal:** **Decision of the Opposition Division of the  
European Patent Office posted on 9 May 2018  
revoking European patent No. 2300008 pursuant to  
Article 101(2) and Article 101(3) (b) EPC.**

**Composition of the Board:**

**Chairman** A. Lindner  
**Members:** J. Molina de Alba  
M. Blasi

## Summary of Facts and Submissions

I. European patent No. 2 300 008, based on European patent application No. 09797440.6, was granted with 14 claims. Granted independent claims 1 and 8 read as follows:

*"1. Use of a liquid composition containing glycerol for preparing a medicament for reducing hypoglycemia of fasting human subjects without affecting the respiratory exchange ratio of fasting."*

*"8. A liquid composition containing glycerol for use in reducing hypoglycemia of fasting human subjects without affecting the respiratory exchange ratio of fasting."*

II. The following documents, cited in the opposition and appeal proceedings, are referred to in the present decision:

D2: Das Spektrum der Medizin, H. Bunte and K. Bunte, Schattauer GmbH, 2004, 664/665

D3: Exercise Physiology for Health, Fitness, and Performance, S.A. Plowman and D.L. Smith, Benjamin Cummings, 2<sup>nd</sup> Ed., 2008, 131-134

D4: R.J. Maughan et al., Eur. J. Appl. Physiol, 57, 1988, 570-576

D5: J.M. Miller et al., Medicine and Science in Sports and Exercise, 15(3), 1983, 237-242

D21: G. Brabant et al., Deutsches Arzneiblatt, 95(17), 1998, A1022-A1026

D25: Excerpt from video presentation of the product "GLYCK" by Dr Stephan Lück

III. An opposition was filed against the patent on the grounds that the claimed subject-matter lacked novelty

and inventive step, was not disclosed in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art, and extended beyond the content of the application as filed (Article 100(a), (b) and (c) EPC).

- IV. The present appeal by the patent proprietor (appellant) lies from the decision of the opposition division revoking the patent. The decision was based on the patent as granted and three sets of claims filed as auxiliary requests 1 to 3.

In the decision, the opposition division found in relation to the main request (patent as granted) that the composition of claim 8 lacked novelty over the glycerol liquid compositions disclosed in documents D4 and D5. This resulted from the fact that the reduction of hypoglycaemia in fasting human subjects was considered to be non-therapeutic and therefore did not limit the claimed composition. For the same reason, the composition of claim 8 of auxiliary request 1 was not novel either. Lastly, auxiliary requests 2 and 3 were not admitted into the opposition proceedings.

- V. With the statement of grounds of appeal the appellant requested the acceleration of the proceedings in view of pending infringement proceedings, and filed sets of claims as auxiliary requests 1 to 11. The claims of auxiliary requests 1, 8 and 9 were identical to those of auxiliary requests 1 to 3, respectively, on which the decision was based.

- VI. In letters prior to its reply to the statement of grounds of appeal, the opponent (respondent) requested that the party status of the opponent be transferred from DrSlym GmbH to DrSlym Vital GmbH, provided

evidentiary documents in support of this request and declared that it had no objection to the acceleration of the appeal proceedings requested by the appellant.

Subsequently, with its reply to the statement of grounds of appeal, the respondent filed six documents and arguments for the dismissal of the appeal.

VII. During the appeal proceedings, the board sent three communications to the parties:

In a first communication dated 7 November 2018, the board gave its preliminary opinion that the transfer of the opponent status to DrSlym Vital GmbH could be acknowledged on the basis of the evidence provided.

In a second communication dated 5 February 2019, it informed the parties that the request for acceleration had been allowed.

Lastly, in a communication pursuant to Article 15(1) RPBA dated 8 May 2019 sent in preparation for the oral proceedings, which were scheduled in view of the parties' requests to that effect, the board raised doubts on the novelty of the subject-matter claimed in the patent as granted and in auxiliary requests 1 to 3. It also noted that the admission of auxiliary requests 2 to 11 needed to be discussed.

VIII. After the board's communication in preparation for the oral proceedings was issued, the appellant filed sets of claims as auxiliary requests 1 to 19 to replace the auxiliary requests previously on file (auxiliary requests 8 to 15 were subsequently withdrawn at the oral proceedings before the board; auxiliary requests

16 to 19 are identical to auxiliary requests 8 to 11 filed with the statement of grounds of appeal).

Claims 1 and 8 of auxiliary request 1 differ from claims 1 and 8 as granted in that the amount of glycerol in the liquid composition has been specified to be of **at least 0.2 mol/l**.

Claims 1 and 8 of auxiliary request 2 differ from claims 1 and 8 as granted in that the use is carried out **without disturbing the metabolic state of fasting**.

Claims 1 and 8 of auxiliary request 3 differ from claims 1 and 8 as granted in that they contain the two features added to claim 1 of auxiliary requests 1 and 2.

Claim 1 of auxiliary requests 4 to 7 are identical to claim 1 as granted and claim 1 of auxiliary requests 1 to 3, respectively.

Claim 1 of auxiliary request 16 reads as follows:

*"1. Non-therapeutic use of a liquid composition containing glycerol for reducing hypoglycemia of fasting human subjects without affecting the respiratory exchange ratio of fasting."*

Claim 1 of auxiliary request 17 differs from claim 1 of auxiliary request 16 in that the amount of glycerol in the liquid composition has been specified to be of **at least 0.2 mol/l**.

Claim 1 of auxiliary request 18 differs from claim 1 of auxiliary request 16 in that the use is carried out **without disturbing the metabolic state of fasting**.

Claim 1 of auxiliary request 19 differs from claim 1 of auxiliary request 16 in that it contains the two features added to claim 1 of auxiliary requests 17 and 18.

- IX. Oral proceedings were held before the board on 26 September 2019. At the oral proceedings, the appellant withdrew its pending auxiliary requests 8 to 15 and filed new sets of claims as auxiliary requests 20 to 23. The new sets of claims were identical to auxiliary requests 4 to 7 filed with the statement of grounds of appeal.

Claim 1 of auxiliary request 20 reads as follows:

*"1. Use of a liquid composition containing glycerol for reducing hypoglycemia of fasting human subjects without affecting the respiratory exchange ratio of fasting."*

Claim 1 of auxiliary request 21 differs from claim 1 of auxiliary request 20 in that the amount of glycerol in the liquid composition has been specified to be of **at least 0.2 mol/l**.

Claim 1 of auxiliary request 22 differs from claim 1 of auxiliary request 20 in that the use is carried out **without disturbing the metabolic state of fasting**.

Claim 1 of auxiliary request 23 differs from claim 1 of auxiliary request 20 in that it contains the two features added to claim 1 of auxiliary requests 21 and 22.



- X. The appellant's arguments, where relevant to the present decision, may be summarised as follows:

*Therapeutic character of the use in claim 8 as granted*

Pathologic hypoglycaemia is a clinical situation which arises when blood glucose levels fall below 45 mg/dl (see document D2, page 664, right-hand column). It manifests itself by the occurrence of symptoms such as ravenous hunger, perspiration, tremor, confusion, seizures, etc. (see document D2, page 665, left-hand column, and document D21, page A1023), and is a serious condition which requires immediate medical treatment. The patent in suit does not relate to that type of hypoglycaemia but to the non-pathologic hypoglycaemic state induced by fasting in healthy subjects. This physiologically induced hypoglycaemia is the one referred to in the summary of document D4 and arises at blood glucose levels below 4 mmol/l (75 mg/dl). Nevertheless, it is accompanied by the same symptoms as pathologic hypoglycaemia. This hypoglycaemic state is also the one mentioned in document D21 (page A1022, abstract and right-hand column), which notes that blood glucose levels of healthy fasting subjects may fall to levels even below 45 mg/dl without this situation being considered to be pathologic hypoglycaemia.

Thus, although the physiologically induced hypoglycaemia on which the patent is based is not a pathology, the respondent's interpretation that it might only cause a feeling of hunger and that this might be removed just by eating some bread is medically unfounded; fasting causes not only ravenous hunger, which represents a severe medical situation that cannot be equated with usual hunger, but also symptoms which

are generally associated with pathologies (perspiration, tremor, confusion, seizures, etc.). This is reflected in the sentence on page 5, lines 5-7 of the application as filed, which states that the liquid compositions according to the invention can be used in medical applications. Contrary to the respondent's opinion, document D25 does not call into question the medical character of the claimed use, since it does not disclose a liquid composition according to the patent in suit and, more importantly, does not deal with hypoglycaemia. Even in the theoretical, non-existent situation that fasting caused only hunger, the claimed use would still be therapeutic as a method to prevent the occurrence of pathologic symptoms. Moreover, unlike the provision of bread, the reduction of hypoglycaemia according to the patent (i.e. by the administration of glycerol) reduces the pathology-related symptoms of fasting without affecting the fasting state, a state which is characterised by its respiratory exchange ratio (see D3, page 133, left-hand column, first full paragraph, and Table 5-4) and is medically desirable for its beneficial effects on the subject's health.

Thus, the use defined in claim 8 as granted is therapeutic in two respects: it reduces symptoms generally associated with pathologies and, at the same time, it maintains the subject in a fasting state - a temporary prophylactic state aimed at preventing diseases.

*Therapeutic character of the use in claim 1 as granted*

If the use defined in claim 8 were considered to encompass both therapeutic and non-therapeutic methods of treatment, the use of claim 1, which refers to a medicament, would exclude non-therapeutic methods.

*Novelty - claim 8 as granted*

A correct interpretation of hypoglycaemia within the meaning of the invention leads to the conclusion that the use defined in claim 8 is therapeutic, and so the use features are limiting. Hence, as documents D4 and D5 do not disclose the treatment of hypoglycaemia in fasting individuals, the subject-matter of claim 8 is novel over the glycerol solutions of documents D4 and D5.

*Novelty - claim 8 of auxiliary requests 1 to 3*

For the same reason, the subject-matter of claim 8 of each of auxiliary requests 1 to 3 is novel over the content of documents D4 and D5, too.

*Novelty - claim 1 of auxiliary request 4*

Even if the use recited in claim 1 were considered to be non-therapeutic and therefore non-limiting, there is no reason to disregard other features in the claim. In particular, the term "medicament", which is a composition feature, cannot be disregarded when considering the question of novelty. As neither of document D4 nor D5 discloses the preparation of a medicament, the subject-matter of claim 1 has to be acknowledged as being novel.

*Novelty - claim 1 of auxiliary requests 5 to 7*

The arguments put forward in relation to claim 1 of auxiliary request 4 are equally applicable to claim 1 of each of auxiliary requests 5 to 7. The subject-matter claimed in those requests is therefore novel.

Admission of auxiliary requests 16 and 17

Auxiliary requests 16 and 17 (filed as auxiliary requests 8 and 9 with the statement of grounds of appeal) are identical to auxiliary requests 2 and 3 filed during the oral proceedings before the opposition division. In not admitting them into the proceedings, the opposition division did not exercise its discretion correctly:

The filing of the requests was triggered by the new arguments from the respondent filed with its letter of 23 February 2018, i.e. two weeks prior to the oral proceedings before the opposition division. The arguments for the first time introduced the discussion of whether the use recited in the claims was purely therapeutic or whether it encompassed non-therapeutic applications; they were also accompanied by the citation and discussion of case law. Before that point in time, the appellant had no reason to file claims directed to only a non-therapeutic use.

Contrary to the respondent's allegation, point 8 of the summons to oral proceedings by the opposition division did not raise this issue in relation to the Swiss-type claims. From the opposition division's opinion, the appellant could sense that there might be a problem with the novelty of the composition of claim 8 (purpose-related product claim), but not that this would also affect claims 1 to 7, formulated in the Swiss-type format. Hence, the new requests, directed to non-therapeutic uses and filed at the earliest occasion, i.e. with the statement of grounds of appeal, were a legitimate response to the respondent's arguments and to the decision under appeal.

Admission of auxiliary requests 18 and 19

Auxiliary requests 18 and 19 are also directed to non-therapeutic uses. They were filed with the statement of grounds of appeal as auxiliary requests 10 and 11, respectively. Similarly to auxiliary requests 16 and 17, auxiliary requests 18 and 19 were filed in order to deal with the new twist on the issue of novelty introduced by the respondent two weeks before the oral proceedings before the opposition division and should therefore be admitted into the appeal proceedings.

Admission of auxiliary requests 20 to 23

Auxiliary requests 20 to 23 have been filed in response to the board's surprising conclusion during the oral proceedings that the uses claimed in the previous requests are purely non-therapeutic; the decision under appeal, the respondent's arguments and the board's preliminary opinion provided in its communication dated 8 May 2019 considered that the claims encompassed both therapeutic and non-therapeutic uses. The board's communication in particular had suggested that only granted claim 8 was problematic. Auxiliary requests 20 to 23 respond to that new situation and do it in a convergent manner. As these claim requests had already been filed with the statement of grounds of appeal (as then auxiliary requests 4 to 7), the respondent could not have been surprised by their content either. Hence, they should be admitted into the appeal proceedings.

XI. The respondent's arguments, where relevant to the present decision, may be summarised as follows:

*Therapeutic character of the use in claim 8 as granted*

Claim 8 does not mention the treatment of any disease or symptom; it merely refers to a reduction of hypoglycaemia in fasting human subjects. The application as filed, however, does not define what is meant by reducing hypoglycaemia in fasting human subjects; it merely teaches (page 5, lines 1-2) that the gist of the invention is supporting fasting subjects, namely by stabilising blood glucose concentrations using glycerol (page 3, lines 23-24). The example in the patent illustrates the administration of glycerol to subjects in a fasting state after an overnight fast; it discloses neither a hypoglycaemic state nor associated symptoms. Hence, the only possible interpretation of the reduction of hypoglycaemia according to claim 8 that can be derived from the application is the support of fasting subjects. In view of the example of the patent, this support might consist merely of a reduction of the perception of hunger in healthy subjects after an overnight fast. As such a use neither treats a disease nor alleviates symptoms of pain and suffering, it cannot be considered to be therapeutic.

In addition, the claimed non-therapeutic treatment may be distinguished from therapeutic indications on account of the subjects treated (healthy fasting subjects vs patients suffering from a pathologic condition of hypoglycaemia).

According to the appellant, hypoglycaemia within the meaning of the patent is a non-pathologic state induced in healthy fasting subjects, characterised by blood glucose levels of below 75 mg/dl, and which is accompanied by pathology-related symptoms. The application, however, is completely silent on the nature of that hypothetical physiologically induced hypoglycaemia and on any of the accompanying symptoms that would need to be treated. That sort of hypoglycaemia and its symptoms are not disclosed in the prior art either. By contrast, (pathologic) hypoglycaemia and its symptoms were well known to the skilled person at the priority date (see documents D2 and D21). Thus, the appellant is trying to read features from claim 8 which are neither in the claim nor in the application as filed and which did not form part of the common general knowledge at the priority date.

The appellant's argument that the hunger experienced during fasting would be a medical condition has to be rejected because there is no evidence that a condition other than usual hunger arises in the hypothetical non-pathologic hypoglycaemia described by the appellant. The occurrence of pathology-related symptoms in healthy subjects after an overnight fast, as illustrated in the patent example, would be particularly unlikely; the skilled person's knowledge is that ravenous hunger and pathology-related symptoms appear when blood glucose levels fall below 45 mg/dl, i.e. in pathologic hypoglycaemic states (see document D21).

*Therapeutic character of the use in claim 1 as granted*

The wording of claim 1 as a Swiss-type claim does not make any difference with regard to the therapeutic

character of the treatment. The reference to a medicament cannot render the claimed treatment therapeutic since it does not relate to the treatment of any disease.

*Novelty - claim 8 as granted*

In view of its lack of therapeutic character, the use recited in claim 8 cannot be considered to be limiting. Thus, claim 8 is directed to a glycerol-containing liquid composition that is suitable for the claimed purpose, i.e. stabilising blood glucose concentrations of fasting human subjects without affecting the respiratory exchange ratio. The glycerol solutions described in any of documents D4 and D5 fulfil these conditions and therefore anticipate the claimed liquid compositions.

*Novelty - claim 8 of auxiliary request 1*

The restriction in claim 8 of auxiliary request 1 to liquid compositions containing at least 0.2 mol/l glycerol does not change the situation of novelty with regard to documents D4 and D5, since the glycerol content in the solutions of those documents is above that level.

*Novelty - claim 8 of auxiliary requests 2 and 3*

Claim 8 of each of auxiliary requests 2 and 3 results from the addition of the feature "without disturbing the metabolic state of fasting" to claim 8 of the main request and auxiliary request 1, respectively. As the use in each new claim 8 remains non-therapeutic, the new feature cannot be considered to be limiting. Hence, for the reasons put forward in relation to claim 8 of



the main request and auxiliary request 1, the subject-matter of claim 8 of each of auxiliary requests 2 and 3 also lacks novelty over the glycerol solutions disclosed in documents D4 and D5.

Novelty - claim 1 of auxiliary request 4

There is no basis in the case law to treat Swiss-type claims differently to purpose-related product claims according to Article 54(5) EPC. In particular, there is no basis for the approach that the term "medicament" in a Swiss-type claim may introduce a limitation when the claimed use is non-therapeutic; the case law is consistent in that when no medical treatment is claimed, the claim cannot be formulated in the Swiss-type format. According to G 5/83 (section 21 and point 2 of the order), if the use recited in the claim is not therapeutic, the claim has to be interpreted as being directed to a method for the preparation of a composition; this is standard practice.

Thus, claim 1 of auxiliary request 4 has the same scope as claim 8 of the main request and its subject-matter is not novel over the glycerol solutions of documents D4 and D5.

Novelty - claim 1 of auxiliary requests 5 to 7

Claim 1 of each of auxiliary requests 5 to 7 correspond to claim 8 of each of auxiliary requests 1 to 3, respectively, formulated in the Swiss-type format. Thus, for the same reasons as with claim 8 of each of auxiliary requests 1 to 3, the subject-matter of claim 1 of each of auxiliary requests 5 to 7 also lacks novelty over the glycerol solutions of documents D4 and D5.

Admission of auxiliary requests 16 and 17

Auxiliary requests 16 and 17 are identical to auxiliary requests 2 and 3 filed before the opposition division. They were not admitted by the opposition division, which exercised its discretion correctly. As may be derived from point 5.1 of the decision under appeal, the opposition division followed the right criteria when refusing to admit the requests. These requests should have been filed at the latest in reply to the summons to oral proceedings by the opposition division in view of point 8 of the annex to the summons. The filing of these requests at the appeal stage leads to a situation in which the board has to consider issues for the first time, running counter to the function of the board as the review instance. The re-filing of these requests with the statement of grounds of appeal cannot be said to have been provoked by the decision of the opposition division either.

Admission of auxiliary requests 18 and 19

The reasons why the opposition division did not admit auxiliary requests 16 and 17 into the opposition proceedings are also applicable to auxiliary requests 18 and 19. Therefore, they should not be admitted into the appeal proceedings either.

The requests are intended to solve an aspect of the problem of novelty in relation to documents D4 and D5 which was on file at least from the summons to oral proceedings sent by the opposition division (section 8, point 2). The fact that the respondent cited related case law cannot be used as an excuse for filing new requests; the cited case law was broadly known and

extracted from the publication "Case Law of the Boards of Appeal", 8th edition 2016, pages 47/48. Therefore, the requests could and should have been filed earlier. Moreover, the new feature "without disturbing the metabolic state of fasting" introduced in claim 1 of each of auxiliary requests 18 and 19 raises issues that were not discussed in the proceedings before the opposition division and does not change the situation with regard to the objection of lack of novelty in relation to documents D4 and D5.

#### Admission of auxiliary requests 20 to 23

Like auxiliary requests 16 to 19, auxiliary requests 20 to 23 try to deal with the issue that claim 1 in each of them is directed to a non-therapeutic use. However, that point of discussion was already on file in the opposition proceedings and was dealt with in the decision under appeal (point 5.1 of the decision). Hence, the requests should have been filed earlier.

Furthermore, auxiliary requests 20 to 23 were filed with the statement of grounds of appeal as auxiliary requests 4 to 7 and were subsequently withdrawn with the letter of 26 August 2019. The appellant's filing of previously abandoned requests at the oral proceedings before the board took the respondent by surprise. The claims are also not *prima facie* allowable and raise new issues under, *inter alia*, Article 84 EPC.

XII. The final requests of the parties were as follows:

- The appellant requested that the decision under appeal be set aside and the opposition be rejected or, alternatively, that the patent be maintained in amended form on the basis of any of the sets of

claims filed with the letter dated 26 August 2019 as auxiliary requests 1 to 7 and 16 to 19 or on the basis of any of the sets of claims of auxiliary requests 20 to 23 filed at the oral proceedings before the board.

- The respondent requested that the party status of the opponent be transferred from DrSlym GmbH to DrSlym Vital GmbH and that the appeal be dismissed.

XIII. At the end of the oral proceedings, the decision of the board was announced.

### **Reasons for the Decision**

1. The appeal is admissible. It complies with the requirements pursuant to Articles 106 to 108 and Rule 99(2) EPC.

2. *Transfer of opponent status*

A transfer of party status of the opponent from DrSlym GmbH to DrSlym Vital GmbH, Rosental 6, 80331 Munich was requested in the course of the appeal proceedings.

The evidence submitted to the board, together with the evidence submitted during the opposition proceedings and additionally relied upon in support of the requested transfer, showed that both the assets in the interests of which the opposition had been filed and the opponent status had been transferred from DrSlym GmbH to Leluna UG (haftungsbeschränkt (limited

liability)), and that the latter had changed its name to DrSlym Vital GmbH. Hence, the board could acknowledge the transfer of the opponent status to DrSlym Vital GmbH.

This finding, already anticipated in the board's communication dated 7 November 2018, had not been contested by the appellant either.

3. *Therapeutic character of the use in claim 8 as granted*

3.1 Claim 8 of the patent as granted relates to the use of glycerol for reducing hypoglycaemia in fasting human subjects. The technical background underlying this use is the appellant's observation that the glycerol administered to fasting subjects is slowly metabolised into glucose in such a way as to not increase blood glucose levels. This mechanism is supported by the results of the example in the patent depicted in Figures 1 and 2 (see also paragraph [0011]). This has not been disputed by the respondent.

According to the appellant, as glycerol is metabolised into glucose without increasing blood glucose levels, it would not trigger insulin production, and the glucose produced from glycerol would be available only for the brain. This would then lead to a reduction of the hypoglycaemia symptoms produced by a lack of glucose in the brain.

3.2 Hypoglycaemia is generally known as a clinical condition characterised by glucose blood levels of below 45 mg/dl and the occurrence of concomitant symptoms such as craving, sweating, tremor, etc. (see document D2, page 664, right-hand column, and page 665, left-hand column; and document D21, page A1022, right-

hand-column, and page A1023). That condition represents a serious pathologic state which has to be treated immediately.

It was common ground between the parties that glycerol is not suitable for treating that clinical condition because the metabolism of glycerol into glucose is too slow to provide the required fast increase of blood glucose levels. Therefore, the parties agreed that the hypoglycaemia referred to in the patent could not be the generally known pathologic or clinical hypoglycaemia.

Under these circumstances, in order to assess whether the use defined in claim 8 is therapeutic, the actual meaning of hypoglycaemia in the context of the patent first needs to be established.

- 3.3 As noted by the respondent, although hypoglycaemia within the meaning of the patent is not to be understood as clinical hypoglycaemia, the application as filed does not contain any definition of hypoglycaemia. The symptoms that would be associated with that non-pathologic or physiologically induced hypoglycaemia are not mentioned either. The only teaching found in the application in that respect is that:

*"[s]ince adequate glycerol supplementation during fasting improves glucose availability, it reduces undesirable effects such as hypoglycaemia..."* (page 2, lines 4/5),

*"adequate amounts and concentrations of glycerol can be used to stabilize blood glucose"*

*concentrations in fasting subjects..."* (page 3, lines 23/24), or

*"[t]he present invention describes use of glycerol in liquid preparation and liquid composition for supporting fasting subjects..."* (page 5, lines 1/2).

Example 1 in the application as filed, which is the example in the patent, makes a comparative study of the respiratory exchange ratio and blood glucose levels of healthy subjects when a carbohydrate or glycerol is administered after an overnight fast.

Hence, neither the patent nor the application on which it is based contains any information about what hypoglycaemia actually means.

3.4 Turning to the prior art, the board also fails to find any generally known non-pathologic or physiologically induced type of hypoglycaemia.

In this context, the appellant indicated that the hypoglycaemia referred to in the patent was physiologically induced in healthy subjects by fasting; it appeared at blood sugar levels which are not considered to correspond to hypoglycaemia, namely below 75 mg/dl, but presents the same symptoms of pathologic hypoglycaemia (i.e. craving, sweating, tremor, etc.). This hypoglycaemia was the one mentioned in the summary of document D4, characterised by blood glucose levels of below 4 mmol/l (i.e. ~75 mg/dl). It was also supported by the statement in document D21, page A1022, right-hand column, which teaches that, under fasting conditions, healthy subjects may exhibit blood glucose

levels of below 45 mg/dl (i.e. pathologic hypoglycaemic levels) without being in (pathologic) hypoglycaemia.

The board, however, cannot derive from those documents that there is a type of hypoglycaemia which is physiologically induced in healthy subjects, occurs at blood glucose levels which are not considered to be hypoglycaemic (i.e. 45 mg/dl or above) and is nevertheless accompanied by the symptoms characteristic of clinical hypoglycaemia. The board rather concludes the opposite:

Document D4 is a paper containing a specific study on the metabolism of glucose and glycerol in fasting subjects subjected to prolonged exercise. Firstly, it is noted that this document cannot be considered to represent the common general knowledge in the art for hypoglycaemia. Secondly, it does not even contain a definition of hypoglycaemia and its symptoms. The document merely states in its summary that none of the subjects submitted to the study became hypoglycaemic and, immediately after that statement, in parentheses, it gives a blood glucose concentration range of below 4 mmol/l. In the absence of further information, that passage of document D4 cannot qualify as a definition of a type of hypoglycaemia that is generally known and different from the generally accepted definition of clinical hypoglycaemia.

Conversely, document D21 is an informative paper on hypoglycaemia in adults, drafted for training purposes ("Zur Fortbildung") and containing on page A1022 a precise definition of hypoglycaemia. This document may be considered to represent the common general knowledge in the art.



According to document D21 (page A1022, right-hand column) the diagnosis of (clinical) hypoglycaemia requires not only the finding of blood glucose levels below 45 mg/dl, but also the occurrence of its typical symptoms and their improvement after provision of glucose. This appears to be necessary since, under fasting conditions, healthy subjects may exhibit blood glucose values below 45 mg/dl.

From this passage of document D21, it is clear that fasting subjects may have blood glucose levels as low as 45 mg/dl and nevertheless not present symptoms of hypoglycaemia. This teaching is in contradiction with the appellant's contention that there exists a physiologically induced hypoglycaemia characterised by blood glucose levels above the hypoglycaemic range (i.e. above 45 mg/dl) concomitant with the occurrence of symptoms typical of hypoglycaemia.

- 3.5 Following from the above, neither the application as filed nor the prior art supports the appellant's argument that there is a physiologically induced hypoglycaemia which causes the typical symptoms of hypoglycaemia at non-hypoglycaemic blood glucose levels.

Thus, the board agrees with the respondent that the only possible interpretation of "reducing hypoglycaemia" according to the patent is supporting fasting subjects through stabilising blood glucose concentrations. The use defined in claim 8 neither treats a disease nor alleviates any pathology-related symptoms; it merely reduces the perception of hunger and, therefore, it cannot be considered to be therapeutic.

3.6 Regarding the appellant's argument that the claimed method was therapeutic because fasting was a prophylactic treatment for preventing diseases, the board notes that claim 8 is directed not to the (prophylactic) treatment of any disease by fasting, but rather to the reduction of hypoglycaemia as a consequence of fasting. In addition, the appellant himself stated that the fasting subjects were healthy, and the patent does not contain any indication that would lead to the conclusion that fasting within the meaning of the invention has any therapeutic aim. This is reinforced by the fact that the only example in the patent illustrates an overnight fast. Thus, considering that fasting may have purposes other than preventing diseases (aesthetics, hunger strike, etc.) and that fasting according to the invention may last only one night, the board cannot accept that fasting within the meaning of the patent in suit is a therapeutic indication.

4. *Therapeutic character of the use in claim 1 as granted*

Claim 1 defines essentially the same subject-matter as claim 8, only it is formulated in the so-called "Swiss-type" format, as instituted by the Enlarged Board of Appeal in decisions G 1/83, G 5/83 and G 6/83 (see OJ EPO 1985, 60 et seq., point 2 of each order). A use which is purely non-therapeutic cannot be rendered therapeutic by the fact that the "Swiss-type" wording makes reference to a medicament. This is clear from point 2 of the order of decision G 5/83, which states that "[a] European patent may be granted with claims directed to the use of a substance or composition for the manufacture of a medicament for a specified new and inventive therapeutic application." Thus, if the

application recited in the Swiss-type claim is not therapeutic, point 2 of the order does not apply.

5. *Novelty - claim 8 as granted*

Following the above, the use defined in claim 8 limits the claimed liquid glycerol composition only to the extent that the composition needs to be suitable for the mentioned use. In other words, claim 8 is directed to a glycerol-containing liquid composition which is suitable for reducing hypoglycaemia in fasting human subjects without affecting the respiratory exchange ratio of fasting.

Document D4 discloses (see abstract) a study which assesses the influence that a 36-hour fast followed by the provision of glucose, glycerol or a placebo has on the metabolism and performance of men during prolonged exercise. According to the section "Materials and methods" on page 571, the glycerol solution administered to the subjects of the study contained 1 g per kg body weight in a total volume of 400 ml. Considering that the men who took part in the study weighted  $69.8 \pm 3.2$  kg, the glycerol solution had a concentration of approximately 175 g/l (70 g/0.4 l), i.e. 1.9 mol/l.

Similarly, document D5 presents (see abstract) the results of an evaluation of the effect that feeding glycerol has on protecting subjects against the development of hypoglycaemia during prolonged exercise. The authors of D5 found that the provision of a glycerol solution increased glycerol blood concentration but did not alter the respiratory exchange ratio. As described on page 238 (left-hand column, second full paragraph and right-hand column,

second paragraph) glycerol was administered to the subjects after an overnight fast as a solution containing 1 g glycerol per kg of body weight mixed with 300 ml of a flavoured water solution. The subjects submitted to the study were of two different weights:  $70.5 \pm 3.6$  kg and  $62.8 \pm 1.6$  kg. Accordingly, the solutions provided in the tests of D5 had a glycerol concentration of approximately 235 g/l or 210 g/l, i.e. 2.6 mol/l or 2.3 mol/l, respectively.

The glycerol solutions of documents D4 and D5 are suitable for reducing hypoglycaemia in fasting subjects within the meaning of the invention (i.e. supporting fasting subjects) without affecting the respiratory exchange ratio of fasting. This is apparent from the fact agreed upon by the parties that the property of not affecting the respiratory exchange ratio of fasting can be ascribed directly to glycerol (see also paragraph [0011] of the patent). Hence, the glycerol solutions disclosed in documents D4 and D5 comprise all the features of claim 8 as granted and therefore anticipate its subject-matter (Article 100(a) and Article 54 EPC).

6. *Novelty - claim 8 of auxiliary request 1*

Claim 8 of auxiliary request 1 differs from claim 8 of the main request only in that it specifies the concentration of glycerol in the liquid composition to be of at least 0.2 mol/l. As explained above, the glycerol solutions disclosed in documents D4 and D5 contain 1.9, 2.6, or 2.3 mol/l. Thus, they also anticipate the subject-matter of claim 8 of auxiliary request 1 (Article 54 EPC).

7. *Novelty - claim 8 of auxiliary requests 2 and 3*

Claim 8 of each of auxiliary requests 2 and 3 differs from claim 8 of each of the main request and auxiliary request 1 in that they contain the additional feature "without disturbing the metabolic state of fasting".

Similarly to the feature "without affecting the respiratory exchange ratio of fasting" in claim 8 of the main request and auxiliary request 1, it was common ground that the property of not disturbing the metabolic state of fasting is attributable to glycerol (see also paragraph [0011] of the patent). Hence, the glycerol solutions disclosed in documents D4 and D5 are also suitable for fulfilling the new condition imposed by claim 8 of each of auxiliary requests 2 and 3. Consequently, the subject-matter of claim 8 of auxiliary requests 2 and 3 is not novel either (Article 54 EPC).

8. *Novelty - claim 1 of auxiliary request 4*

Claim 1 of auxiliary request 4 corresponds to claim 8 of the main request (patent as granted), formulated in the Swiss-type format. As noted in point 4 above, a use which is purely non-therapeutic cannot be rendered therapeutic merely by the fact that the wording of claim 1 in the Swiss-type format makes reference to a medicament. This is directly derivable from decisions G 1/83, G 5/83 and G 6/83 (supra), which instituted the claims formulated in the Swiss-type format and which require the claimed use to be therapeutic in order for it to be considered as limiting. This is clear from point 2 of the order and from the last paragraph of

point 21 of the reasons of decision G 5/83, which states:

*"It is to be clearly understood that the application of this special approach to the derivation of novelty can only be applied to claims to the use of substances or compositions intended for use in a method referred to in Article 52(4) EPC."*

It should be noted that the provision of Article 52(4) EPC cited in the passage is that of the EPC1973, which corresponds to present Article 53(c) EPC (2000). The methods referred to in both articles and relevant in the present case are the *"methods for treatment of the human or animal body by surgery or therapy..."*

The appellant argued that even if the use defined in claim 1 was considered to be non-therapeutic, the claim was directed to the preparation of a medicament and that this feature (medicament) could not be ignored, regardless of the nature of its use (therapeutic or not).

The board disagrees. As the use of claim 1 is not therapeutic, the special derivation of novelty mentioned above does not apply. Instead, the term "medicament" has to be interpreted in the light of the claimed use; in the present case it is equivalent to a composition suitable for administration to the human or animal body for obtaining the claimed non-therapeutic effect. Such compositions are disclosed in documents D4 and D5. Reading additional and in particular therapeutic aspects from said term would be contradictory to the claimed use. Therefore, the disclosures of documents D4 and D5 anticipate the

subject-matter of claim 1 of auxiliary request 4 pursuant to Article 54 EPC.

9. *Novelty - claim 1 of auxiliary requests 5 to 7*

Claim 1 of each of auxiliary requests 5 to 7 corresponds to claim 8 of auxiliary requests 1 to 3, respectively, formulated in the Swiss-type format.

As for claim 1 of auxiliary request 4, the use recited in claim 1 of each of auxiliary requests 5 to 7 is not therapeutic. Hence, for the reasons given in relation to claim 1 of auxiliary request 4, the subject-matter of claim 1 of each of auxiliary requests 5 to 7 lacks novelty (Article 54 EPC) over the glycerol compositions of documents D4 and D5.

10. *Admission of auxiliary requests 16 and 17*

10.1 The claims of auxiliary requests 16 and 17 are identical to those of auxiliary requests 2 and 3 filed by the appellant at the oral proceedings before the opposition division. They were not admitted by the opposition division, a decision taken in exercise of their discretion.

10.2 In such a situation, it is not the function of the board to review all the facts and circumstances of the case as if it were in the place of the opposition division in order to decide whether or not it would have exercised the discretion in the same way. Rather, a board should only overrule the way in which the opposition division has exercised its discretion if it comes to the conclusion that the opposition division has done so according to the wrong principles, or without taking the right principles into account, or in

an unreasonable way, and has thus exceeded the proper limits of its discretion (similar, but in the context of *ex parte* proceedings, see G 7/93, point 2.6 of the reasons).

- 10.3 The sets of claims of auxiliary requests 2 and 3 in the opposition proceedings were filed by the appellant in the afternoon of the oral proceedings on 9 March 2018, in order to overcome an objection of lack of novelty in relation to documents D4 and D5. The objection was based on the fact that the use in granted claims 1 and 8 was not limiting because it was not therapeutic, i.e. it was not a method excluded by Article 53(c) EPC (see also Article 54(5) EPC).

The opposition division considered that the requests had been filed too late in the proceedings because the issue of lack of novelty in connection with Article 53(c) EPC had been on file since 12 January 2017. In addition, the requests introduced complex issues that could not be dealt with without sufficient preparation, such as the change of claim category and the introduction of an undisclosed disclaimer. Hence, the requests were not admitted into the proceedings by the opposition division.

- 10.4 In the statement of grounds of appeal, the appellant contested this decision arguing that, prior to the oral proceedings before the opposition division, the objection of lack of novelty in relation to Article 53(c) EPC, including a discussion of the relevant case law, had not been fully substantiated.
- 10.5 The board disagrees because the question of the limiting effect of the use in granted claims 1 and 8 and its importance for the assessment of novelty was



introduced by the respondent (as the opponent) in section C.I of its letter dated 12 January 2017, entitled "Keine zweite medizinische Indikation" (no second medical indication). The letter had been sent to supplement the notice of opposition. Furthermore, this issue was extensively discussed by the parties in all of their subsequent letters (12 July 2017, item II.3; 17 August 2017, item B; 9 January 2018, item III; 9 January 2018, pages 2-3; and 23 February 2018, item IV, 1.1.7 and 1.1.8). In addition, the opposition division's communication in preparation for the oral proceedings drew attention to this point (see item 8). As such, the board fails to see that there was any change to the respondent's case or any surprise to the appellant shortly before or during the oral proceedings before the opposition division. In particular, the argument that there had been new developments in the case because the respondent's letter sent prior to the oral proceedings had referred to board of appeal decisions hitherto not been mentioned is not convincing. The point in support of which these decisions were cited had been made by the respondent from the outset.

Despite the clear dispute on this issue and its importance for the outcome of the opposition proceedings, the appellant chose to react only with arguments and did not file auxiliary requests 2 and 3 until the afternoon of the oral proceedings held on 9 March 2018. Thus, the opposition division did not exceed the proper limits of its discretion.

10.6 Accordingly, in not admitting auxiliary requests 2 and 3, the opposition division did not exercise its discretion according to the wrong principles, or without taking the right principles into account, or in

an unreasonable manner. In particular, there is no reason to criticise the aspects taken into account by the opposition division in the exercise of its discretion, namely the late stage of the proceedings at which the requests had been filed, the creation of new issues and the procedural fairness towards the other party.

Consequently, the board confirms the opposition division's decision not to admit auxiliary requests 2 and 3 into the opposition proceedings.

Furthermore, the decision under appeal was not based on any new aspects which would have made it possible to consider the resubmission of these requests as then auxiliary requests 8 and 9 (present auxiliary requests 16 and 17) together with the statement of grounds of appeal as a legitimate reaction to the decision under appeal.

Thus, the board excluded auxiliary requests 16 and 17 from the appeal proceedings in accordance with Article 12(4) RPBA.

11. *Admission of auxiliary requests 18 and 19*

These requests were filed with the statement of grounds of appeal as auxiliary requests 10 and 11. Their claim 1 is based on claim 1 of auxiliary requests 16 and 17, respectively, to which the feature "*without disturbing the metabolic state of fasting*" has been added.

The board takes the view that their filing cannot be considered a legitimate reaction to the decision under appeal.

The board agrees with the respondent that the discussion of the novelty of the subject-matter of claim 1 of auxiliary requests 18 and 19 in relation to the disclosures of documents D4 and D5 would be essentially the same as that of claim 1 of auxiliary requests 16 and 17, respectively, i.e. of auxiliary requests 2 and 3, which were not admitted into the proceedings by the opposition division.

The board also agrees with the respondent that the reasons why the opposition division did not admit these auxiliary requests into the opposition proceedings are equally relevant for auxiliary requests 18 and 19; specifically, they introduce a change of category and a disclaimer with no basis in the application as filed in order to overcome the objection of lack of novelty in relation to documents D4 and D5 due to the fact that the use in granted claims 1 and 8 was not limiting because it was not therapeutic. This issue had been on file from an early stage of the opposition proceedings (see point 10.5 above).

The fact that the respondent cited case law in this respect does not justify the filing of new requests, since the cited case law was well known and extracted from the Case Law of the Boards of Appeal, 8th edition 2016, pages 47/48.

In view of the above, the appellant could and should have filed such claim requests during the proceedings before the opposition division.

In consequence, the board excluded auxiliary requests 18 and 19 from the appeal proceedings in accordance with Article 12(4) RPBA.

12. Admission of auxiliary requests 20 to 23

Auxiliary requests 20 to 23 were filed by the appellant with the statement of grounds of appeal as auxiliary requests 4 to 7. They were abandoned with the letter dated 26 August 2019 and then re-filed at the oral proceedings before the board. The subject-matter of the claims of auxiliary requests 20 to 23 is identical to that of auxiliary requests 16 to 19 (auxiliary requests 16 and 17 in turn being identical to auxiliary requests 2 and 3, which were not admitted into the proceedings by the opposition division); only the disclaimer "non-therapeutic", which during the oral proceedings before the board turned out to be superfluous was removed in auxiliary requests 20 to 23.

Like auxiliary requests 16 to 19, auxiliary requests 20 to 23 address the issue that claim 1 as granted had been found to be directed to a non-therapeutic use and the related consequences for the assessment of novelty in relation to the disclosures of documents D4 and D5. However, as set out in the context of auxiliary requests 16 to 19 (see points 10 and 11 above), this point of discussion had formed already a central part of the opposition proceedings from an early stage, as also explained in the decision under appeal (see point 5.1 of the decision). Hence, the requests could and should have been filed earlier, namely during the proceedings before the opposition division.

The board cannot agree with the appellant's argument that the board's communication dated 8 May 2019 might have suggested that only granted claim 8 was problematic in relation to novelty as the point in

question (point 9) refers to both claims 1 and 8, as also confirmed by point 10 of the communication.

The further aspects addressed by the parties (namely whether or not the claim requests were convergent and their filing history at the appeal stage, i.e. having been submitted with the statement of grounds of appeal then replaced and subsequently resubmitted at the oral proceedings) were considered by the board to be of no relevance in the circumstances of the present case, in which these claim requests should in fact have been presented during opposition proceedings.

Hence, the board, exercising its discretion under Article 13 RPBA, decided not to admit auxiliary requests 20 to 23 into the appeal proceedings.

## Order

### For these reasons it is decided that:

1. The status as opponent was validly transferred to DrSlym Vital GmbH.
2. The appeal is dismissed.

The Registrar:

The Chairman:



M. Schalow

A. Lindner

Decision electronically authenticated