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# Datasheet for the decision of 12 September 2023

**Case Number:** T 1416/21 - 3.3.02

**Application Number:** 11789282.8

**Publication Number:** 2576578

**IPC:** C07H3/06, C07H1/06, A61K31/702, A61P31/00

**Language of the proceedings:** EN

**Title of invention:**
POLYMORPHS OF 2'-O-FUCOSYLLACTOSE AND PRODUCING THEREOF

**Patent Proprietor:**
Glycom A/S

**Opponent:**
BASF SE

**Headword:**
GLYCOM / POLYMORPHS / 2'-O-FUCOSYLLACTOSE

**Relevant legal provisions:**
EPC Art. 54, 56

**Keyword:**
Novelty
Inventive step

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**Beschwerdekammern**

**Boards of Appeal**

**Chambres de recours**

Boards of Appeal of the
European Patent Office
Richard-Reitzner-Allee 8
85540 Haar
GERMANY
Tel. +49 (0)89 2399-0
Fax +49 (0)89 2399-4465

**Case Number: T 1416/21 - 3.3.02**

# D E C I S I O N
# of Technical Board of Appeal 3.3.02
# of 12 September 2023

| | |
|---|---|
| **Appellant:** (Patent Proprietor) | Glycom A/S<br>Kogle Allé 4<br>2970 Hørsholm (DK) |
| **Representative:** | Strych, Sebastian<br>Mitscherlich PartmbB<br>Patent- und Rechtsanwälte<br>Karlstraße 7<br>80333 München (DE) |
| **Respondent:** (Opponent) | BASF SE<br>Carl-Bosch-Str. 38<br>67056 Ludwigshafen (DE) |
| **Representative:** | Altmann Stößel Dick Patentanwälte PartG mbB<br>Isartorplatz 1<br>80331 München (DE) |
| **Decision under appeal:** | **Decision of the Opposition Division of the European Patent Office posted on 1 July 2021 revoking European patent No. 2576578 pursuant to Article 101(3)(b) EPC.** |

**Composition of the Board:**

| | |
|---|---|
| **Chairman** | M. Maremonti |
| **Members:** | A. Lenzen |
| | P. Guntz |

## Summary of Facts and Submissions

I. This decision concerns the appeal filed by the patent proprietor (appellant) against the opposition division's decision (decision under appeal) to revoke European patent No. 2 576 578 (patent).

II. Reference is made in the present decision to the following documents filed with the opposition division:

D1 Kuhn, R. et al., Chem. Ber. 1956, page 2513
D6 Byrn, S. et al., Pharmaceutical Research 1995, Vol. 12, No. 7, pages 945 to 954
D12 EP 2 072 052 A1
D21 Beijing QingXi Technology Research Institute, Experimental Report (34 pages)

III. The decision under appeal is based on the patent as granted (main request), the sets of claims of auxiliary requests 1 to 3, filed by letter dated 5 May 2021, and the set of claims of auxiliary request 4, filed during the oral proceedings before the opposition division.

The opposition division came, *inter alia*, to the following conclusions:

- The subject-matter of claim 1 as granted and claim 1 of auxiliary requests 1 and 2 was not novel over the disclosure in document D1.
- The subject-matter of claim 1 of auxiliary request 3 did not involve an inventive step in view of document D12 taken as the closest prior art.

Furthermore, the opposition division decided not to admit auxiliary request 4 into the proceedings.

IV. With the statement of grounds of appeal, the appellant contested the opposition division's reasoning. It also filed the sets of claims of auxiliary requests 1 to 9.

V. In its reply to the statement of grounds of appeal, the opponent (respondent) rebutted the appellant's arguments.

VI. In preparation for the oral proceedings, which had been arranged at the parties' request, the board issued a communication pursuant to Article 15(1) RPBA 2020.

VII. The oral proceedings before the board were held on 12 September 2023 by videoconference in the presence of both parties. At the end of the oral proceedings, the chair announced the order given in the present decision.

VIII. Summaries of the appellant's arguments on the allowability of the main request and auxiliary requests 1 to 9 are contained in the reasons for the decision.

IX. The respondent's arguments on the allowability of the main request and auxiliary requests 1 to 9, insofar as relevant to the present decision, can be summarised as follows.

- Method 2 of D1 represented an enabling disclosure. Experiment 1 of D21 was a proper repeat of method 2 of D1, i.e. a repeat which the skilled person would have carried out having their common general knowledge in mind. The product of experiment 1 of

D21 showed the XRPD peaks provided for in claim 1 of the main request and auxiliary requests 1 to 9. Further, D1 started from pure 2'-O-fucosyllactose ("2'-FL" in the following for brevity) for its crystallisation methods and disclosed that no other sugars could be detected in the mother liquors after crystallisation. There was, therefore, no reason to assume that, by following the teaching of D1, and in particular that of method 2, a pure product was not obtained. The result of experiment 1 of D21 shifted the burden of proving that D1 did not disclose a 2'-FL polymorph as required by claim 1 of the main request and auxiliary requests 1 to 9 to the appellant.

- In view of the foregoing, the subject-matter of claim 1 of the main request and auxiliary requests 1 and 2 was not novel over D1.
- D12 was the prior art closest to the subject-matter of claim 1 of auxiliary requests 3 to 9. The subject-matter of claim 1 of these requests differed from the embodiment of claims 1, 2, 4 and 5 of D12 only in that it was directed at a specific polymorph of 2'-FL and, if applicable, in that this polymorph contained only a limited amount of impurity. The distinguishing feature(s) could at most be associated with a lower hygroscopicity. It was common general knowledge that hygroscopic ingredients reduced the storage stability of the compositions to which they were added and tended to clump together. Hence, against the background of this common general knowledge, the skilled person would have added in an obvious manner a non-hygroscopic form of 2'-FL to the embodiment of D12 when seeking to solve the objective technical problem formulated by the appellant. D1 disclosed such a non-hygroscopic form of 2'-FL in the form of

the product of method 2. This form was also highly pure. Although the non-hygroscopicity was referred to in D1 only after the description of method 3, this could not be understood to mean that only the crystals obtained by method 3 were non-hygroscopic. This was because method 3 used the crystals obtained by method 2 as seeds. The crystals obtained by methods 2 and 3, therefore, had to have the same properties. Hence, the subject-matter of claim 1 of auxiliary requests 3 to 9 did not involve an inventive step.

X. The parties' final requests at the end of the oral proceedings which are relevant to the present decision were as follows:

- The appellant requested that the decision under appeal be set aside and the opposition be rejected, implying that the patent be maintained as granted (main request). Alternatively, it requested that the patent be maintained in amended form based on one of the sets of claims of auxiliary requests 1 to 9, filed with the statement of grounds of appeal.

  The sets of claims of auxiliary requests 1 to 4 are identical to those of auxiliary requests 1 to 4 on which the decision under appeal is based. Since auxiliary request 4 was not admitted by the opposition division (see above), the resubmission of auxiliary request 4 on appeal implied the request that it be admitted.

- The respondent requested that the appeal be dismissed, implying that the revocation of the patent be confirmed. It also requested that the

opposition division's decision not to admit auxiliary request 4 be confirmed and that auxiliary requests 5 to 9, filed with the appellant's statement of grounds of appeal, not be admitted.

## Reasons for the Decision

Auxiliary request 2 - Claim 1 - Novelty (Article 54 EPC)

1. Claim 1 of auxiliary request 2 reads as follows:

> "*Crystalline 2'-O-fucosyllactose polymorph II, characterized in that it displays X-ray powder diffraction reflections, based on a measurement using CuKα radiation, at 16.98±0.20, 13.65±0.20, 18.32±0.20, 21.70±0.20, 15.22±0.20, 20.63±0.20 and 11.94±0.20 2θ angles, wherein the crystalline 2'-O-fucosyllactose polymorph II contains less than 5 w/w% of impurity.*"

Thus, in brief, claim 1 relates to a crystalline form of 2'-FL characterised by the seven specific XRPD reflections and the recited purity degree.

2. The respondent put forward a novelty objection to the subject-matter of claim 1 based on D1.

3. D1 addresses the problem of providing crystalline 2'-FL. It states (lines 1 to 6) that purification of 2'-FL by repeated chromatography or via its tosylhydrazone does not immediately yield crystalline 2'-FL. Rather, a syrup or, after treatment with alcohol, an amorphous white powder is obtained first.

3.1 According to D1 (lines 6 to 10), crystalline 2'-FL can be obtained from the above-mentioned syrupy 2'-FL as follows (denoted as "method 1" by the parties):

> "*Nach längerem Aufbewahren von 2.1 g eines mit Wasser abgedampften Sirups bei ~20° schieden sich am oberen Teil der Kolbenwand einige weiße Kriställchen ab, mit deren Hilfe sich der gesamte Sirup über Nacht in ein lockeres Kristallpulver verwandeln ließ.*"
> [translation by the board: After storing 2.1 g of a water-evaporated syrup for an extended period of time at approximately 20°, some white crystals separated at the upper part of the wall of the flask, with the help of which the entire syrup could be transformed into a loose crystalline powder overnight.]

3.2 D1 further discloses (lines 10 to 17) that, starting from amorphous 2'-FL, crystalline 2'-FL can be obtained as follows (denoted as "method 2" by the parties):

> "*Ein anderer Ansatz, in dem nach mehrwöchigem Aufbewahren bei +4° spontan Kristallisation eintrat, war durch Lösen von amorphem Trisaccharid in wasserhaltigem Methanol und Zugabe des gleichen Volumens n-Butanol sowie einiger Tropfen n-Hexylalkohol bereitet.*"
> [translation by the board: Another approach, in which spontaneous crystallisation occurred after several weeks of storage at +4°, was conducted by dissolving amorphous trisaccharide in aqueous methanol and adding an equal volume of n-butanol along with a few drops of n-hexyl alcohol.]

3.3 Finally, D1 states (lines 19 to 22) that crystalline 2'-FL can also be obtained by using the crystalline products of the above two methods as seed crystals in the following method (denoted as "method 3" by the parties):

> "*Besitzt man Impfkristalle, so läßt sich die Fucosido-lactose (1 g) durch Lösen in heißem 75-proz. Methanol (20 ccm) und allmähliche Zugabe von absol. Äthanol (60-80 ccm) leicht in schönen dreieckigen Plättchen (Abbild.) vom Schmp. 230-231° (Zers.) erhalten.*"
> [translation by the board: If seed crystals are available, fucosido-lactose (1 g) can be easily obtained as nice triangular plates (see image) with a melting point of 230-231° (decomposition) by dissolving the crystals in hot 75% methanol (20 ccm) and gradually adding absolute ethanol (60-80 ccm).]

3.4 The above understanding of D1, i.e. that method 3 uses the crystals of method 1 or 2 as seeds, is consistent with the summary of D1 in paragraph [0003] of the patent and was also common ground between the parties at the oral proceedings before the board.

3.5 With respect to the crystalline 2'-FL obtained, D1 also states (lines 22 to 23) that it is non-hygroscopic.

This property of the crystalline 2'-FL is mentioned in D1 only after the description of method 3. Contrary to the appellant's view, however, this does not mean that this property characterises only the crystals resulting directly from method 3. In the present case, the crystals obtained by method 1 or 2 are used as seed crystals in method 3 (see above). This means that the

crystals of method 3 are obtained from these seed crystals by further growth. Therefore, the board concurs with the respondent that it is not apparent why the crystals from method 3 should have different properties than those resulting from method 1 or 2. In summary, D1 can only be understood as meaning that the above property (non-hygroscopic) characterises the crystals of 2'-FL no matter which of the three disclosed methods is used.

4. D1 does not disclose XRPD reflections of the crystals from any method or the degree of their purity in w/w%. However, this does not mean that its disclosure cannot be novelty-destroying. To the extent that the teaching of D1 is sufficient for the skilled person, in light of their common general knowledge, to obtain the product of claim 1 (in other words: if D1 provides an enabling disclosure for the product of claim 1), D1 would be novelty-destroying to claim 1.

4.1 In this context, experiment 1 of D21 (page 2/20) is relevant. It reads as follows (text in square brackets added by the board):

> "*In order to repeat the Method 2 in Literature 1* [D1] *the following experiment was carried out: 2.527 g of amorphous 2-FL* [2'-FL] *was dissolved in 100 ml of aqueous methanol (99 ml of anhydrous methanol + 1 ml of water), and the white solids were gradually dissolved under continuous stirring, the liquid became a white turbid liquid, and then 100 ml of n-butanol was added, and more white solids were precipitated. The solution was filtered to obtain a colorless transparent solution, and then 400 µl of n-hexanol was added to the filtrate, and shaken. The solution was transferred to a*

*250 ml conical flask, sealed with a parafilm perforated with several small holes, and stored at 4 °C for 2 weeks. The crystalline product was filtered, washed with methanol, and dried in vacuo to obtain 0.314 g of white crystals.*"

4.2 The board agrees with the respondent that experiment 1 of D21 is a proper repeat of method 2 of D1, i.e. a repeat which the skilled person would have carried out having their common general knowledge in mind. In particular, in both method 2 of D1 and experiment 1 of D21, amorphous 2'-FL is dissolved in a certain volume of aqueous methanol and the solution is diluted with the same volume of *n*-butanol. Afterwards, a few drops of *n*-hexanol are added and crystallisation is carried out at 4 °C.

4.3 As is evident from figure 4 and table 1 of D21 (pages 10/20 and 11/20), the crystals obtained from this repeat show the XRPD reflections recited in claim 1. This was also never disputed by the appellant.

4.4 Furthermore, as already set out above, D1 uses a 2'-FL as the starting material for its crystallisations which had previously been purified by repeated chromatography or via its tosylhydrazone. D1 (last sentence) also states that no other sugars could be detected in the mother liquors by paper chromatography after crystallisation.

Against this background, at least in the absence of any evidence to the contrary, which the appellant did not provide, the board is convinced that the crystalline 2'-FL obtained according to the disclosure of D1 and in particular method 2 does not contain any impurities.

5. The appellant submitted that D1 did not disclose method 2 in an enabling manner. In this respect, it referred to paragraph [0016] of the patent, stating that the inventors of the patent had never been able to reproduce the methods described in D1. Decisions T 325/16 and T 605/02 were relevant in this context. In particular, the appellant argued that several pieces of information were lacking in D1 so that especially method 2 might not be reproduced. Experiment 1 of D21 filled in these gaps in the disclosure of method 2 of D1. Contrary to D21, D1 did not specify the amounts of solvents or 2'-FL used nor did it exactly specify the number of drops of *n*-hexanol added or the storage time; moreover, D21 disclosed that the liquid became a white turbid liquid, an item of information that was not mentioned in D1. Therefore, several additional assumptions had been made in D21 that could not be derived from D1 nor from the skilled person's common general knowledge. The appellant also pointed to the fact that, according to D21, the crystalline product was obtained after only two weeks, whereas D1 disclosed the obtention of the crystals after "several weeks".

Furthermore, the appellant referred to D6 and submitted that it was evident from figure 1 of D6 (page 946) that several parameters such as e.g. choice of solvent, temperature, concentration, agitation and pH all had an effect on the type of polymorphic form that was obtained from a solution during crystallisation. Therefore, it was entirely conceivable that the polymorph as defined in claim 1 had been obtained in D21 by selecting appropriate operating conditions that were not mentioned in D1 but that only slight changes in the crystallisation conditions of experiment 1 of D21 would have resulted in a different polymorph.

Hence, the appellant argued that D21 was not a proper repeat of method 2 of D1 and therefore it could not be concluded that the 2'-FL polymorph of claim 1 was necessarily obtained when following the teaching of method 2 of D1.

6. The board is not convinced by these arguments for the following reasons.

6.1 It is clear that method 2 of D1 is not described to the very last detail. However, this does not allow the conclusion that the method is necessarily not disclosed in an enabling manner. In the present case, the board is convinced that the skilled person, having their common general knowledge in mind, would have known how to put method 2 of D1 into practice. The appellant's arguments are not suitable for casting doubt on this for the following reasons.

6.1.1 First of all, both the storage time at 4 °C (2 weeks) and the amount of n-hexanol (400 µL, i.e. about 8 drops) reported in D21 are fully in line with the disclosure of method 2 in D1 ("nach mehrwöchigem Aufbewahren" [translation by the board: after several weeks of storage], "sowie einiger Tropfen *n*-Hexylalkohol" [translation by the board: along with a few drops of n-hexyl alcohol]). In the absence of evidence to the contrary, which the appellant did not put forward, the board sees no reason to doubt that the skilled person would very well have chosen the storage time and number of drops of *n*-hexanol as stated in experiment 1 of D21.

6.1.2 Secondly, it is true that the amounts of solvents and 2'-FL used in experiment 1 of D21 are not disclosed in D1. However, the skilled person is well aware that any

compound which is to be crystallised from a solvent or a solvent system has a certain solubility at a certain temperature in said solvent (system). Consequently, depending on the amount of compound to be crystallised, the skilled person would have used only those amounts of solvent(s) which result in a concentration of the compound to be crystallised which is above the solubility limit at the crystallisation temperature, because no crystallisation at all could otherwise have been achieved. In simpler terms, as argued by the respondent, the skilled person would have known how much solvent to use depending on the amount of 2'-FL to be crystallised. This is what has been done in experiment 1 of D21.

6.1.3 Thirdly, D21 also states that "*the liquid became a white turbid liquid*" upon dissolution of the amorphous 2'-FL in aqueous methanol. The appellant pointed to the fact that this observation is not described in method 2 of D1. This argument implies that according to the appellant, the solution in D1 must have been clear upon dissolution of the amorphous 2'-FL in aqueous methanol. However, in the absence of evidence to the contrary, which the appellant did not provide, the board sees no reason for this assumption. In fact, according to experiment 1 of D21 (*loc. cit.*), a clear solution is obtained by filtration. Thus, the board is satisfied that this is exactly what the skilled person would have done by following method 2 of D1 if they had wanted to prepare a solution from which a compound was to be crystallised.

6.2 Therefore, the appellant's arguments cannot change the conclusion above that method 2 of D1 is disclosed in an enabling manner and that experiment 1 of D21 is a proper repeat of method 2 of D1, i.e. a repeat which

the skilled person would have carried out having their common general knowledge in mind.

6.3 In view of the above, the mere assertion in the patent that the appellant tried in vain to repeat the methods of D1 is not convincing. In fact, as submitted by the respondent, the appellant has not provided any details concerning the operating conditions that might have been used in these attempts to reproduce the methods of D1 and which would not have allowed crystallised 2'-FL to be obtained.

6.4 It may be that, as argued by the appellant with reference to D6, a slight modification of the crystallisation conditions of experiment 1 of D21 could have in principle resulted in a different polymorph. However, the allegation that such is exactly the case here has never been proven by the appellant and, thus, amounts to mere speculation.

6.5 The appellant also referred to decisions T 325/16 and T 605/02, arguing that a polymorph disclosed in the prior art in a non-enabling manner could not be novelty-destroying. The board had already pointed out the lack of relevance of these decisions in its communication pursuant to Article 15(1) RPBA 2020 (see point 3.4.8). This is because the underlying facts were different from the facts at hand. Moreover, as set out above, the board is convinced that the polymorph defined in claim 1 is disclosed in D1 in an enabling manner. At the oral proceedings before the board, the appellant no longer relied on these decisions in its argumentation. Hence, the board sees no reason to comment on them further.

7. Therefore, the board concludes that method 2 of D1 is disclosed in an enabling manner and that it results in the claimed 2'-FL polymorph without any impurities. Hence, the subject-matter of claim 1 of auxiliary request 2 is not novel over D1. Auxiliary request 2 is not allowable.

Main request and auxiliary request 1 - Claim 1 - Novelty (Article 54 EPC)

8. Claim 1 of auxiliary request 1 differs from claim 1 of auxiliary request 2 only in that it allows for a higher degree of impurity ("*less than 10 w/w% of impurity*" in claim 1 of auxiliary request 1 vs. "*less than 5 w/w% of impurity*" in claim 1 of auxiliary request 2). Claim 1 of the main request (claim 1 as granted) does not set any limit to the amount of impurity.

Therefore, the subject-matter of claim 1 of auxiliary request 2 is fully encompassed by the subject-matter of claim 1 of the main request and auxiliary request 1. The above reasoning of lack of novelty for the subject-matter of claim 1 of auxiliary request 2 therefore also applies to the subject-matter of claim 1 of the main request and auxiliary request 1.

It follows that the subject-matter of claim 1 of these requests is not novel over D1 and therefore the main request and auxiliary request 1 are not allowable.

Auxiliary request 9 - Claim 1 - Inventive step (Article 56 EPC)

9. Claim 1 of auxiliary request 9 reads as follows:

> "*An infant formula comprising crystalline 2'-O-fucosyllactose polymorph II being characterized in*

*that it displays X-ray powder diffraction reflections, based on a measurement using CuKα radiation, at 16.98±0.20, 13.65±0.20, 18.32±0.20, 21.70±0.20, 15.22±0.20, 20.63±0.20 and 11.94±0.20 2θ angles, wherein the crystalline 2'-O-fucosyllactose polymorph II contains less than 0.1 w/w% of impurity, wherein the infant formula contains 2'-O-fucosyllactose polymorph II in a total amount of 0.1 to 3.0g/100g formula.*"

Closest prior art

10. There was agreement between the parties that D12 is the prior art closest to the subject-matter of claim 1 of auxiliary request 9. The board sees no reason to take a different view.

D12 (embodiment of claims 1, 2, 4 and 5) discloses an infant formula comprising 2'-FL in an amount of from 0.1 to 3 g/100g formula.

Distinguishing features

11. According to the appellant, the subject-matter of claim 1 differed from D12 in that the infant formula comprised the specific polymorph of 2'-FL of claim 1 instead of amorphous 2'-FL and in that said polymorph contained less than 0.1 w/w% of impurity.

Objective technical problem

12. The appellant argued that the polymorph of 2'-FL recited in claim 1 was less hygroscopic than amorphous 2'-FL. On the one hand, this resulted in higher storage stability. On the other hand, hygroscopic ingredients tended to clump together before they were used to make

a formulation. As a result, the use of the 2'-FL polymorph of claim 1 resulted in a more homogeneous distribution in the formula than the use of the more hygroscopic amorphous 2'-FL. Consequently, the objective technical problem was to provide a formula with a more homogeneous distribution of 2'-FL which was more storage stable.

It is assumed, in the appellant's favour, that this formulation of the objective technical problem is correct.

Obviousness of the claimed solution

13. As put forward by the respondent and not disputed by the appellant, it is common general knowledge that hygroscopic ingredients tend to clump together and reduce the storage stability of the compositions to which they are added.

Consequently, against the background of this common general knowledge, the skilled person facing the objective technical problem posed would have tried to replace the amorphous 2'-FL of D12 with a less hygroscopic form of 2'-FL. To do so, they would have turned to D1, which discloses a non-hygroscopic form of 2'-FL in method 2 (see point 3.5 above), prepared this form and included it in the formula of D12. As already set out above, there is no reason to assume that the product of method 2 of D1 is not pure. The skilled person would consequently have arrived at the subject-matter of claim 1 of auxiliary request 9 in an obvious manner. The fact that there are also other non-hygroscopic forms of 2'-FL besides the one disclosed in D1, as pointed out by the appellant, merely shows that there would have been other obvious solutions to the

objective technical problem. However, the selection of one of several obvious solutions does not involve an inventive step.

It follows that the subject-matter of claim 1 of auxiliary request 9 does not involve an inventive step within the meaning of Article 56 EPC and that auxiliary request 9 is not allowable.

Auxiliary requests 3 to 8 - Claim 1 - Inventive step (Article 56 EPC)

14. Claim 1 of auxiliary requests 3 to 8 differs from claim 1 of auxiliary request 9 in that:

- it is directed to a nutritional formulation instead of an infant formula (auxiliary requests 3 to 6)
- it allows for a higher amount of impurities (auxiliary requests 3 to 5, 7 and 8)
- it does not contain any limitation with regard to the amount of the 2'-FL polymorph II in the formulation/formula (auxiliary requests 3 to 6)

Therefore, the subject-matter of claim 1 of auxiliary request 9 is fully encompassed by the subject-matter of claim 1 of each of auxiliary requests 3 to 8. In particular, a nutritional formulation fully encompasses an infant formula, see also paragraph [0047] of the patent, according to which the latter is a preferred embodiment of the former.

The above reasoning regarding lack of inventive step of the subject-matter of claim 1 of auxiliary request 9 therefore also applies to the subject-matter of claim 1 of auxiliary requests 3 to 8.

It follows that the subject-matter of claim 1 of these requests lacks an inventive step and that auxiliary requests 3 to 8 are not allowable.

15. The respondent had requested that the opposition division's decision not to admit auxiliary request 4 be confirmed and that auxiliary requests 5 to 9 not be admitted into the proceedings. In view of the non-allowability of auxiliary requests 4 to 9, there was no need for the board to decide on these requests from the respondent.

Conclusion

16. None of the appellant's claim requests is allowable.

**Order**

**For these reasons it is decided that:**

The appeal is dismissed.

The Registrar: The Chairman:

M. Schalow M. Maremonti

Decision electronically authenticated