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Datasheet for the decision of 2 February 2022

Case Number: T 0755/16 - 3.3.02

Application Number: 08784774.5

Publication Number: 2170949

IPC: C07K16/00, C07K1/34

Language of the proceedings: EN

Title of invention:
VARIABLE TANGENTIAL FLOW FILTRATION

Patent Proprietor:
F. Hoffmann-La Roche AG

Opponent:
Baxter Healthcare S.A.

Headword:

Relevant legal provisions:
EPC Art. 56
RPBA 2020 Art. 13(2)

Keyword:
Inventive step
Amendment to appeal case
Amendment after summons
Late-filed facts
Late-filed objection

Decisions cited:

Catchword:
A request not to admit a certain document, this request having been filed for the first time during oral proceedings before the board, may constitute an amendment of the appeal case the admittance of which is governed by Article 13(2) RPBA 2020 (point 3 of the reasons)

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Case Number: T 0755/16 - 3.3.02

D E C I S I O N
of Technical Board of Appeal 3.3.02
of 2 February 2022

Appellant: (Patent Proprietor)	F. Hoffmann-La Roche AG 124 Grenzacherstrasse 4070 Basel (CH)
Representative:	Mewburn Ellis LLP Aurora Building Counterslip Bristol BS1 6BX (GB)
Appellant: (Opponent)	Baxter Healthcare S.A. Thurgauerstrasse 130 8152 Glattpark/Opfikon (CH)
Representative:	Alt, Michael Bird & Bird LLP Maximiliansplatz 22 80333 München (DE)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 28 January 2016 concerning maintenance of the European Patent No. 2170949 in amended form.**

Composition of the Board:

Chairman	M. O. Müller
Members:	S. Bertrand
	P. de Heij

Summary of Facts and Submissions

I. The appeals by the opponent and the patent proprietor lie from the opposition division's interlocutory decision that European patent No. 2 170 949 in amended form according to the then pending auxiliary request 2, which had been filed during the oral proceedings, met the requirements of the EPC.

II. The then pending auxiliary request 2 contained eleven claims, claim 1 of which read as follows:

"*1. Method for concentrating an immunoglobulin solution by tangential flow filtration, characterized in that the transmembrane pressure and the cross-flow are variable and changed during the filtration process depending on the immunoglobulin concentration with*

i) a transmembrane pressure of from 1.4 bar to 1.6 bar and a cross-flow of from 225 liters/m^2/h to 270 liters/m^2/h in a concentration range up to 30 mg immunoglobulin per ml of solution to be concentrated,
ii) a transmembrane pressure of from 0.8 bar to 0.9 bar and a cross-flow of from 420 liters/m^2/h to 480 liters/m^2/h in a concentration range of from 15 mg/ml up to 55 mg/ml,
iii) a transmembrane pressure of from 0.8 bar to 0.9 bar and a cross-flow of from 360 liters/m^2/h to 420 liters/m^2/h in a concentration range of from 50 mg/ml up to 275 mg/ml,

wherein the actual concentration of the immunoglobulin in the solution to be concentrated determines the applied transmembrane pressure and cross-flow and the

transmembrane pressure and cross-flow are adjusted depending on the actual concentration of the immunoglobulin;
and wherein the membrane area is 0.02 m^2."

III. The following documents are referred to in the present decision:

D4 Luo, R. *et al.*, BioProcess International (2006), pp. 44-46

A018 Expert declaration by Dr. Wolfgang Teschner of 1 June 2016

A028 Third expert declaration by Dr. Wolfgang Teschner

A029 Biotek - Application Note: Paul Held, "Rapid Critical Micelle Concentration (CMC) Determination Using Fluorescence Polarization"

A030 Scientific & Technical Report - Pall Corporation: Diafiltration: "A Fast, Efficient Method for Desalting, or Buffer Exchange of Biological Samples"

A031 Platts, L. and Falconer, R.J. (2015) "Controlling protein stability: Mechanisms revealed using formulations of arginine, glycine and guanidinium HCl with three globular proteins", International Journal of Pharmaceutics, 486 (1-2), pp. 131-135

A032 Masato Kiyoshi *et al.* (2019), "Collaborative Study for Analysis of Subvisible Particles Using Flow Imaging and Light Obscuration: Experiences in Japanese Biopharmaceutical Consortium" Journal of Pharmaceutical Sciences, 2019 (108), pp. 832-841

A033 Eurofins - "Particulate Matter and Particle Size Testing"

A034 USP <788> "Particulate Matter in Injections"

A035 Mutschler Arzneimittelwirkungen, Lehrbuch der Pharmakologie und Toxikologie, 2001, 8, Wissenschaftliche Verlagsgesellschaft, p. 913

A036 Migone *et al.*, "Raxibacumab for the Treatment of Inhalational Anthrax", July 9, New Engl J Med 2009; 361, 2, pp. 135-144

IV. The opposition division came, *inter alia*, to the conclusion that claim 1 of the then pending auxiliary request 2 involved an inventive step.

V. In its statement setting out the grounds of appeal, the opponent submitted document A018 (denoted D16 by the opponent).

VI. Since the opponent and the patent proprietor were both appellant and respondent in the present appeal proceedings, they are referred to in the following as "patent proprietor" and "opponent".

VII. The board issued a communication in preparation for the oral proceedings which had been scheduled as requested by the parties.

VIII. Oral proceedings before the board were held by videoconference on 2 February 2022.

IX. The parties' final requests were as follows:

The opponent requested that the decision under appeal be set aside and that the patent be revoked.

The patent proprietor requested that:

- the decision under appeal be set aside and that the patent be maintained on the basis of the claims of

the main request, filed with the letter of 1 December 2016,

- or, alternatively, that it be maintained on the basis of one of the claim sets of auxiliary requests 1 to 6, filed with the letter of 1 December 2016, or of auxiliary request 7, filed during the oral proceedings before the board.

X. The opponent's case, where relevant to the present decision, may be summarised as follows:

Inventive step

- The distinguishing features of the subject-matter of claim 1 of auxiliary request 4 as regards D4 as the closest prior art were that the transmembrane pressure (TMP) and the cross-flow were adjusted stepwise during the filtration process with regard to the immunoglobulin concentrations achieved during the process.

- Document A018 showed that the effect relied on by the patent proprietor was not achieved over the whole scope of claim 1 of auxiliary request 4.

- The objective technical problem was the provision of an alternative tangential flow filtration (TFF) method.

- The arbitrary selection of TMP and cross-flow values was not regarded as having inventive merit.

- The subject-matter of claim 1 of auxiliary request 4 did not involve an inventive step.

- The same objection applied to the claims of auxiliary requests 1 to 6.

Admittance of the patent proprietor's request not to admit A018 into the proceedings

- The patent proprietor's request was late-filed and should not be admitted into the proceedings according to Article 13(2) RPBA 2020. A018 was submitted with the statement of grounds of appeal filed in 2016. The patent proprietor should have objected to the admittance of A018 at an earlier stage of the appeal proceedings. The patent proprietor had not justified the late-filing.

Admittance of the allegation of fact that firstly, experiment 1 of A018 is outside of the scope of claim 1 because the immunoglobulin concentration ranges are not respected and secondly, due to this, experiment 1 cannot prove that a process according to claim 1 does not lead to any effect

- The patent proprietor's allegation had not been advanced in the written proceedings. If the board would admit it, the opponent would have additional sufficiency objections.

Admittance of auxiliary request 7

- The set of claims of auxiliary request 7 should not be admitted into the proceedings according to Article 13(2) RPBA 2020. The auxiliary request could have been filed earlier. Exceptional circumstances as required by Article 13(2) RPBA were absent.

XI. The patent proprietor's case, where relevant to the present decision, may be summarised as follows:

Inventive step

- The distinguishing features of the subject-matter of claim 1 of auxiliary request 4 as regards D4 as the closest prior art were that the TMP and the cross-flow were adjusted stepwise during the filtration process with regard to the immunoglobulin concentrations achieved during the process.

- The examples of the patent showed that fewer agglomerates in a certain processing time or the same number of agglomerates in a shorter processing time was achieved. No other conclusion could be reached in light of opponent's data in A018.

- Thus, the objective technical problem was the provision of a TFF method resulting in fewer agglomerates in a certain processing time or the same number of agglomerates in a shorter processing time.

- In view of this problem, the claimed solution was not rendered obvious by D4 or the further cited prior art.

- The subject-matter of claim 1 of auxiliary request 4 involved an inventive step.

Admittance of the patent proprietor's request not to admit A018 into the proceedings

- The patent proprietor's request not to admit A018 into the proceedings, although not filed earlier,

should be admitted into the proceedings according to Article 13(2) RPBA 2020.

Admittance of the allegation of fact that firstly, experiment 1 of A018 is outside of the scope of claim 1 because the immunoglobulin concentration ranges are not respected and secondly, due to this, experiment 1 cannot prove that a process according to claim 1 does not lead to any effect

- The patent proprietor's allegation of fact should be admitted into the appeal proceedings.

- The allegation had been advanced in the reply to the grounds of appeal (paragraph a3) on page 15) and therefore did not constitute an amendment to its case.

Admittance of auxiliary request 7

- The set of claims of auxiliary request 7 was in response to the conclusion of the board concerning the relevance of the experiments of A018. These conclusions did not apply to the subject-matter claimed in auxiliary request 7.

Admittance of documents A028 to A036

- Documents A028 to A036 should not be admitted into the appeal proceedings.

Reasons for the Decision

As during the oral proceedings the issue of inventive step was discussed in the context of auxiliary request 4 and as the board's conclusions were only later during the oral proceedings applied to higher ranking claim requests, the board will first address this auxiliary request in these reasons.

Auxiliary request 4

1. The subject-matter of claim 1 of auxiliary request 4 corresponds to the subject-matter of claim 1 of auxiliary request 2, which was considered by the opposition division in its decision (II, *supra*).

   The claim relates to a method of concentrating an immunoglobulin solution by tangential flow filtration (TFF). The method is characterised in that a specific applied transmembrane pressure (TMP) and a specific cross-flow are adjusted stepwise during the filtration process, depending on the immunoglobulin concentration:

Immunoglobulin concentration (mg/ml)	Transmembrane pressure (bar)	Cross-flow (litres/m^2/h)
up to 30	1.4-1.6	225-270
15-55	0.8-0.9	420-480
50 up to 275	0.8-0.9	360-420

Inventive step

2. The opponent objected to the inventive step of claim 1 of auxiliary request 4 in view of D4 as the closest prior art. It relied on document A018.

3. Admittance of the patent proprietor's request not to admit A018 into the proceedings

During the oral proceedings, the patent proprietor requested that A018 not be admitted into the proceedings.

A018 was submitted by the opponent with the statement of grounds of appeal and comprises two experiments relating to a method of concentrating an immunoglobulin solution by TFF. These experiments were discussed by the patent proprietor in its reply to the grounds of appeal (point 4). The patent proprietor objected to the admittance of A018 neither in its reply to the grounds of appeal nor in its subsequent letters. The request not to admit A018 thus represented an amendment to the patent proprietor's case. The admittance of the request is governed by Article 13(2) RPBA 2020, which applies to the case at hand in accordance with the transitional provisions set out in Article 25(3) RPBA 2020 (the summons to oral proceedings was notified after 1 January 2020).

In accordance with Article 13(2) RPBA 2020, any amendment to a party's appeal case made after notification of a summons to oral proceedings shall, in principle, not be taken into account unless there are exceptional circumstances which have been justified with cogent reasons by the party concerned.

Since A018 was filed with the statement of grounds of appeal, its admittance could have been objected to before the oral proceedings. The board sees no reason, and no reason has been cited by the patent proprietor, why this was not done. There are thus no exceptional circumstances which could justify the request made by the patent proprietor during the oral proceedings.

For these reasons, the board has decided not to admit the patent proprietor's request into the proceedings in accordance with Article 13(2) RPBA 2020.

4. The aim of the patent is to improve flux performance (shorten the overall concentration time) and to reduce aggregate formation (paragraphs [0029] and [0034] of the patent) in a method of concentrating an immunoglobulin solution. A reduced aggregate formation correlates with a higher quality product.

D4 relates to a method for concentrating monoclonal antibodies. The method involves the use of a tangential flow mini-cassette (first full paragraph in the right-hand column on page 44 of D4), implying a TFF process. D4 does not refer to immunoglobulin. However, since immunoglobulin is a monoclonal antibody, the aim of D4 is similar to that of the patent in suit.

Thus, D4 constitutes a suitable closest prior art document in the assessment of the inventive step of the subject-matter of claim 1 of auxiliary request 4.

5. Distinguishing features

D4 discloses a process wherein the TMP and the cross-flow are selected depending on the initial concentration of the antibody in the solution to be concentrated ("*Results and Discussion*" on page 45). During this process, the TMP and cross-flow are kept constant. Hence, no stepwise adjustment of the TMP and cross-flow during the process is disclosed.

As was common ground between the parties, the distinguishing feature of claim 1 of auxiliary request 4 in view of D4 is thus that the TMP and the cross-flow

are adjusted stepwise during the filtration process depending on the immunoglobulin concentration.

6. Objective technical problem

Based on the effect shown in the examples of the patent (comparative methods 1 to 4 compared to method 5 according to claim 1 of auxiliary request 4), the patent proprietor formulated the objective technical problem as being the provision of a TFF method resulting in fewer agglomerates in a certain processing time or the same number of agglomerates in a shorter processing time.

The board does not agree with this formulation of the objective technical problem. As submitted by the opponent, A018 shows that the technical problem as formulated by the patent proprietor is not solved over the whole scope of claim 1 for the following reasons.

Document A018 comprises two experiments. Experiment 1 ("variable method") is a process for concentrating immunoglobulin, comprising a TFF process carried out under variable conditions as follows:

Immunoglobulin concentration in mg/ml	Transmembrane pressure in bar	Cross-flow in ml/min (litres/m^2/h)
up to 30	1.5	85-96 (255-288)
15-55	0.85	159-160 (477-480)
more than 45	0.85	131-133 (393-399)

The total aggregate amount ("Total particles" in the table on page 4 of A018) is 9 539 783 and the immunoglobulin concentration ("Protein (%)") achieved

in 212 min (3h32 min) in experiment 1 is 7.8% (78 mg/ml).

Experiment 2 of A018 is a TFF process carried out under constant conditions: the cross-flow (retentate flow) was maintained at 120-133 ml/min, the feed pressure at 1.0-1.2 bar and the TMP at 0.85 bar.

The total aggregate amount and the immunoglobulin concentration achieved in experiment 2 in 200 min are 11 537 461 and 9.7% (97 mg/ml, table on page 6 of A018), respectively.

The hypothetical time for achieving an immunoglobulin concentration of experiment 2, 9.7%, using the variable conditions of experiment 1 would be more than 212 min (time for achieving a concentration of 7.8%) and is thus longer than the time for achieving the same protein concentration under constant conditions (i.e. 200 min for experiment 2).

A comparison of experiment 1 (using variable conditions) with experiment 2 (using constant conditions) thus reveals that the effect relied upon by the patent proprietor in formulating the objective technical problem is not present over the entire scope of claim 1.

The patent proprietor first of all submitted, based on its technical expert's declarations A019 and A026 and documents A020 to A023, that experiments 1 and 2 of A018 did not reach the same degree of immunoglobulin concentration and that it was not possible to compare the total aggregate amount and the processing time between experiments 1 and 2.

The board is not convinced by the patent proprietor's argument.

It is to be expected that, if experiment 1, which was carried out until an immunoglobulin concentration of 78 mg/ml was reached, had been continued until the same immunoglobulin concentration as in experiment 2 (97 mg/ml) was reached, the total aggregate amount would have further increased such that it would have been higher than the one reported for experiment 2 (11 537 461). More specifically, even if it were accepted that no new agglomerates are formed during this continuation of experiment 1, the aggregate amount in mg/ml, which in fact is an aggregate concentration, would still have increased. This is due to the fact that by increasing the immunoglobulin concentration during the continuation of experiment 1 from 78 mg/ml to 97 mg/ml, the total volume is reduced by 12% and therefore the aggregate concentration would increase by 12% and, thus, would be 11.8×10^6 (9 539 783 x 1.12). This is higher than the total aggregate amount achieved by experiment 2 (11 537 461).

Thus, a comparison of experiments 1 and 2 shows that a longer process time is required by experiment 1 (using variable conditions) to achieve the same immunoglobulin concentration as experiment 2 (using constant conditions). Furthermore, by applying this longer process time until the same immunoglobulin concentration is obtained, a higher and thus disadvantageous total aggregate amount would result.

Second, the patent proprietor submitted that experiments 1 and 2 in A018 were performed in the presence of glycine as a stabilising additive. Such an additive was not present in the examples of the patent. In addition, the TFF system used in A018 was not the same as that used in the examples of the patent. Since the experimental conditions were different from those in the patent, no conclusion could be drawn from the

comparison between the results of A018 and the examples of the patent.

This argument must fail since the above conclusion that the effect relied upon by the patent proprietor is not obtained over the entire scope of claim 1 is not based on any comparison between the results in A018 with those in the patent. On the contrary, what has been compared are two results (experiments 1 and 2) within A018. And these two experiments of A018 were carried out under the same conditions (*inter alia* with the same additive (glycine) and the same TFF system) and only differed from one another by the distinguishing feature over D4, i.e. in that the TMP and the cross-flow are adjusted stepwise in experiment 1.

Third, the patent proprietor submitted that the cross-flow of the first step of experiment 1 (85-96 ml/min, 255-288 litres/m^2/h) was not within the range required by step i) of claim 1 of auxiliary request 4 (225-270 litres/m^2/h) but instead simply overlapped it. For that reason, experiment 1 was not in accordance with claim 1. Experiment 1 could thus not prove that the effect relied upon by the patent proprietor was not obtained over the whole scope claimed.

The board does not agree. It is not credible in view of the small difference between the range of 255-288 litres/m^2/h in experiment 1 and the range of 225-270 litres/m^2/h as required by claim 1 that changing the cross-flow from that in experiment 1 to that defined in claim 1 would change the result obtained in experiment 1 to such an extent that the above conclusion based on the comparison between experiments 1 and 2 would no longer be valid.

6.1 Since the effect relied upon by the patent proprietor is thus not achieved over the entire scope of claim 1, the objective technical problem has to be formulated in a less ambitious way as the provision of an alternative TFF method.

7. Obviousness

The arbitrary selection of TMP and cross-flow values during the process as defined in claim 1 of auxiliary request 4 cannot be regarded as having inventive merit. Such an arbitrary selection implies nothing more than a routine adjustment of these two process parameters. For that reason, the subject-matter of claim 1 of auxiliary request 4 does not involve an inventive step.

7.1 Admittance of the allegation of fact that firstly, experiment 1 of A018 is outside of the scope of claim 1 because the immunoglobulin concentration ranges are not respected and secondly, due to this, experiment 1 cannot prove that a process according to claim 1 does not lead to any effect

During the oral proceedings, the patent proprietor submitted that experiment 1 of A018 was not in accordance with claim 1 since the immunoglobulin concentration ranges according to claim 1 had not been respected in the process described in experiment 1. More specifically, it submitted that the third step in experiment 1 was carried out under a TMP of 0.85 bar and a cross-flow of 131 to 133 ml/min after a concentration of immunoglobulin of more than 4.49%, corresponding to a concentration of 44.9 mg/ml. This concentration in experiment 1 was lower than the concentration required by step iii) of claim 1, which was from 50 to 275 mg/ml. For that reason, experiment 1 was not in accordance with claim 1 and could not

constitute proof that a process according to claim 1 did not lead to any effect.

The patent proprietor's submission represents an allegation of fact which again amends the patent proprietor's appeal case.

As set out above, the admittance of any amendment to a party's appeal case after notification of a summons to oral proceedings is governed by Article 13(2) RPBA 2020. Such amendments must not be taken into account unless there are exceptional circumstances which have been justified with cogent reasons by the party concerned.

The patent proprietor argued that the above submission was already made in the reply to the grounds of appeal (paragraph a3) on page 15) and therefore did not constitute an amendment to its case.

The board does not agree.

The heading of paragraph a3) on page 15 of the reply to the grounds of appeal reads "*The parameters used in E1 and E2 do not match the values in the granted patent*", E1 and E2 being experiments 1 and 2 of A018. The only parameter discussed in that context was the cross-flow required by the first step of the process of claim 1 ("*The stated upper limit of the claimed crossflow range is 90 ml/min. In contrast, the actual retentate flow reported in E1 is 85-96 ml/min.*"). There is, however, in that paragraph of the reply to the grounds of appeal neither an explicit nor an implicit reference to the difference between the immunoglobulin concentration of experiment 1 and that required in step iii) of claim 1.

Thus, the allegation of fact identified above did represent an amendment to the patent proprietor's case.

As set out above, A018 and with it experiments 1 and 2 were filed by the opponent with its statement of grounds of appeal. The patent proprietor could thus have criticised these two experiments at an earlier stage of the appeal proceedings. No reason is apparent to the board, and neither was one cited by the patent proprietor, as to why the patent proprietor's submission was not presented until during the oral proceedings before the board. There are thus no exceptional circumstances justifying the admittance of this submission.

For these reasons, the board has decided not to admit the allegation of fact identified above into the appeal proceedings in accordance with Article 13(2) RPBA 2020.

Main request and auxiliary requests 1 to 3, 5 and 6

8. Claim 1 of the main request reads as follows:

"*1. Method for concentrating an immunoglobulin solution by tangential flow filtration, characterized in that the transmembrane pressure and the cross-flow are variable and changed during the filtration process depending on the immunoglobulin concentration with*

i) a transmembrane pressure of from 1.4 bar to 1.6 bar and a cross-flow of from 225 liters/m^2/h to 270 liters/m^2/h in a concentration range up to 30 mg immunoglobulin per ml of solution to be concentrated,
ii) a transmembrane pressure of from 0.8 bar to 0.9 bar and a cross-flow of from 420 liters/m^2/h to 480 liters/m^2/h in a concentration range of from 15 mg/ml up to 55 mg/ml,
iii) a transmembrane pressure of from 0.8 bar to 0.9 bar and a cross-flow of from 360 liters/m^2/h to

420 liters/m^2/h in a concentration range of from 50 mg/ml up to 275 mg/ml,

wherein the actual concentration of the immunoglobulin in the solution to be concentrated determines the applied transmembrane pressure and cross-flow and the transmembrane pressure and cross-flow are adjusted depending on the actual concentration of the immunoglobulin."

9. Claim 1 of auxiliary request 1 corresponds to claim 1 of the main request, except that the cross-flow values are expressed in ml/min and it has been specified that "*the cross-flow is in ml/min for a membrane area of 0.02 m^2*".

10. Claim 1 of auxiliary request 2 corresponds to claim 1 of the main request, except that the cross-flow has been specified to be 240, 450 and 390 litres/m^2/h in steps i), ii) and iii), respectively.

11. Claim 1 of auxiliary request 3 corresponds to a combination of claims 1 and 2 of auxiliary request 2, i.e. the transmembrane pressure has been specified to be 1.5 or 0.85 bar in steps i), ii) and iii).

12. Claim 1 of auxiliary request 5 corresponds to claim 1 as granted, except that it has been specified that "*the membrane area is 0.02 m^2*".

13. The claims of auxiliary request 6 correspond to the claims as granted.

14. During the oral proceedings, the patent proprietor did not dispute that if the subject-matter of claim 1 of auxiliary request 4 lacked an inventive step, the same objection applied to all claim requests on file.

Thus, the board has concluded that the subject-matter of claim 1 of the main request and of each of auxiliary requests 1 to 3, 5 and 6 does not involve an inventive step in view of D4 for the same reasons as those given for the subject-matter of claim 1 of auxiliary request 4.

15. Admittance of auxiliary request 7

15.1 Auxiliary request 7 was filed during the oral proceedings before the board.

Claim 1 of auxiliary request 7 is a combination of claims 1 and 3 of auxiliary request 4.

15.2 The opponent requested that auxiliary request 7 not be admitted into the appeal proceedings in line with Article 13(2) RPBA 2020.

15.3 The patent proprietor submitted that the claim set according to auxiliary request 7 was filed in response to the conclusion of the board concerning the relevance of the experiments reported in A018.

However A018 and the relevance of the experiments reported therein were already discussed in the patent proprietor's reply to the statement of grounds of appeal. Obviously it could be expected that the board might hold the experiments relevant in spite of the patent proprietor's arguments. Thus, the board's conclusions which essentially follow the arguments of the opponent cannot be seen as a convincing reason to file a further auxiliary request.

Hence, no convincing justification for the submission of the claim set according to auxiliary request 7 at this late stage of the appeal proceedings was provided by the patent proprietor.

15.4 In view of the above, the board has decided not to admit auxiliary request 7 into the appeal proceedings in accordance with Article 13(2) RPBA 2020.

16. Admittance of documents A028 to A036

Documents A028 to A036 were submitted by the opponent with its letter of 6 December 2021.

The patent proprietor requested that these documents not be admitted into the proceedings.

During the oral proceedings, the board decided not to admit these documents into the proceedings. As set out above, the subject-matter of claim 1 of the main request and of auxiliary requests 1 to 6 was found not to involve an inventive step in view of D4 as the closest prior art, even disregarding documents A028 to A036. The decision on inventive step is thus in the opponent's favour, and therefore there is no need to provide reasons for the non-admittance of the opponent's documents.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The patent is revoked.

The Registrar: The Chairman:

N. Maslin M. O. Müller

Decision electronically authenticated