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**Datasheet for the decision of 2 June 2023**

**Case Number:** T 1478/18 - 3.3.04

**Application Number:** 11715567.1

**Publication Number:** 2560682

**IPC:** A61K39/395, A61K9/08, A61L2/10, C07K16/06, A61P31/00

**Language of the proceedings:** EN

**Title of invention:**
Antibody preparations

**Patent Proprietor:**
Biotest AG

**Opponent:**
Strawman Limited

**Headword:**
Antibody preparations/BIOTEST

**Relevant legal provisions:**
EPC Art. 54, 56, 83, 84, 100(c), 123(2), 125
RPBA Art. 12(4)
RPBA 2020 Art. 13(2)

**Keyword:**
Amendments - added subject-matter - main request and auxiliary request 1 (yes)
Sufficiency of disclosure - auxiliary request 2 (yes)
Novelty - auxiliary request 2 (yes)
Inventive step - auxiliary request 2 (yes)
Claims - conciseness - auxiliary request 2 (yes)
Divisional application - double patenting - auxiliary request 2 (no)

**Decisions cited:**
G 0003/14, G 0001/15, G 0004/19

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**Case Number: T 1478/18 - 3.3.04**

# D E C I S I O N
# of Technical Board of Appeal 3.3.04
# of 2 June 2023

| | |
|---|---|
| **Appellant:** (Patent Proprietor) | Biotest AG<br>Landsteinerstr. 5<br>63303 Dreieich (DE) |
| **Representative:** | Daniels, Jeffrey Nicholas<br>Page White & Farrer Limited<br>Bedford House<br>21A John Street<br>London WC1N 2BF (GB) |
| **Appellant:** (Opponent) | Strawman Limited<br>Orchard Lea<br>Horns Lane<br>Combe, Witney<br>Oxfordshire OX29 8NH (GB) |
| **Representative:** | D Young & Co LLP<br>120 Holborn<br>London EC1N 2DY (GB) |
| **Decision under appeal:** | **Interlocutory decision of the Opposition Division of the European Patent Office posted on 13 April 2018 concerning maintenance of the European Patent No. 2560682 in amended form** |

**Composition of the Board:**

| | |
|---|---|
| **Chairwoman** | M. Pregetter |
| **Members:** | B. Rutz |
| | M. Blasi |

## Summary of Facts and Submissions

I. Appeals were lodged by the patent proprietor (appellant-patent proprietor) and the opponent (appellant-opponent) against the decision of the opposition division that European patent No. 2 560 682, in amended form in accordance with auxiliary request 2, met the requirements of the EPC. The patent is entitled "*Antibody preparations*".

II. The patent was opposed on the grounds of Article 100(a) EPC, in relation to novelty (Article 54 EPC) and inventive step (Article 56 EPC), and of Article 100(b) and (c) EPC.

III. The opposition division decided with regard to the main request (patent as granted) and auxiliary request 1 that claims 13 and 14 thereof were directed to subject-matter extending beyond the content of the application as filed (Article 100(c) EPC and Article 123(2) EPC, respectively). The opposition division also decided not to admit documents D45, D45a, D45b, D46, D47, D53 and D55 into the proceedings.

IV. Independent claims 1 and 13 of the patent as granted (main request) read:

"1. An antibody preparation suitable for intravenous administration in humans comprising IgG, IgA and at least 5% IgM antibodies by weight of the total amount of antibodies, wherein the preparation is prepared from human plasma, wherein the antibody preparation has specific complement activating activity, wherein the antibody preparation is prepared by a process which is

capable of a more than $3\log_{10}$ removal of non-enveloped viruses and wherein in an in vitro assay with human serum suitable to determine the ability of the antibody preparation to activate complement unspecifically the antibody preparation generates: (i) substantially no C5a, such that the antibody preparation adjusted to an IgM concentration of 1.72 mg/ml generates less than 200 ng/ml C5a after 60 minutes of the assay; and/or (ii) substantially no C3a, such that the antibody preparation adjusted to an IgM concentration of 1.72 mg/ml generates less than 6000 ng/ml C3a after 60 minutes of the assay."

"13. An antibody preparation comprising at least 15% IgM, more than 5% IgA and more than 40% IgG as percentages of the total amount of antibodies, and comprising less than 1.5% aggregates of 1200kDa or above of the total immunoglobulin content as determined by high performance size exclusion chromatography."

Claim 1 of auxiliary requests 1 and 2 is identical to claim 1 of the main request.

Claim 13 of auxiliary request 1 reads (differences from claim 13 of the main request highlighted by the board):

"13. An antibody preparation suitable for intravenous administration in humans comprising at least 15% IgM, more than 5% IgA and more than 40% IgG as percentages by weight of the total amount of antibodies, wherein the preparation is prepared from human plasma, wherein the antibody preparation has specific complement activating activity, wherein the antibody preparation has an anti-complementary activity of less than 1.0 CH50/mg protein, and wherein the antibody preparation comprises less than 1.5% aggregates of

1200kDa or above of the total immunoglobulin content as determined by high performance size exclusion chromatography."

Claim 13 of auxiliary request 2 reads (differences from claim 13 of the main request highlighted by the board):

"13. An antibody preparation suitable for intravenous administration in humans comprising at least 15% IgM, more than 5% IgA and more than 40% IgG as percentages by weight of the total amount of antibodies, wherein the preparation is prepared from human plasma, wherein the antibody preparation has specific complement activating activity, wherein in an in vitro assay with human serum suitable to determine the ability of the antibody preparation to activate complement unspecifically the antibody preparation generates: (i) substantially no C5a, such that the antibody preparation adjusted to an IgM concentration of 1.72 mg/ml generates less than 200 ng/ml C5a after 60 minutes of the assay; and/or (ii) substantially no C3a, such that the antibody preparation adjusted to an IgM concentration of 1.72 mg/ml generates less than 6000 ng/ml C3a after 60 minutes of the assay, and wherein the antibody preparation comprises less than 1.5% aggregates of 1200kDa or above of the total immunoglobulin content as determined by high performance size exclusion chromatography."

V. During the appeal proceedings both appellants replied to each other's appeals. The appellant-opponent further submitted arguments with a letter dated 20 August 2019. The appellant-patent proprietor further filed arguments with a letter dated 4 October 2019. Both parties, in addition, replied to the communication by the board under Article 15(1) RPBA.

VI. In its statement of grounds of appeal, the appellant-patent proprietor relied on the sets of claims of the patent as granted (main request) and of auxiliary request 1, as dealt with in the decision under appeal.

VII. With its statement of grounds of appeal, the appellant-opponent filed documents D60 to D67.

VIII. With the letter dated 20 August 2019 the appellant-opponent filed document D68 (decision of the opposition division in respect of European patent No. 2 560 691).

IX. The board summoned the parties to oral proceedings as requested and informed them of its preliminary opinion in a communication pursuant to Article 15(1) RPBA.

X. With a letter dated 24 May 2023 the appellant-opponent filed document D69 (communication by board 3.3.10 in case T 293/19).

XI. Oral proceedings before the board took place on 2 June 2023. At the end of the oral proceedings, the Chairwoman announced the board's decision.

XII. The following documents are cited in the present decision:

| | |
|---|---|
| D3 | GB 1006753.6 |
| D4b | EP 2560691 B1 |
| D5b | WO 2011/131786 A2 |
| D10 | US 7186410 |

D12 WO 2009/140236 A2

D15 EP 0450412 A1

D17 US 4318902

D18 US 5190752

D19 US 6136312

D29 European Pharmacopoeia 6th edition, vol. 1, sections 2.6.17 and 2.7.9 (2007)

D45 K. M. Hosseini et al., Med. J. Iran. 17: 315-318 (2004)

D45a Experimental data in relation to D45, 17 pages

D45b Further experimental data in relation to D45, 2 pages

D46 K. M. Hosseini et al., DARU 12: 40-43 (2004)

D53 US 5410025 B

D55 R. Rieben et al. Blood 93, 942-951 (1999)

XIII. The appellant-patent proprietor's arguments, in so far as relevant to the decision, may be summarised as follows.

*Admission of documents*

The opposition division had correctly exercised its discretion with regard to documents D1b, D1c, D1d, D42 to D45, D45a, D45b and D46 to D58 as they had been filed late in opposition.

None of the documents first filed upon appeal (D60 to D69) should be admitted because they were not *prima facie* relevant.

The filing of these documents at the appeal stage was not justified as an immediate and reasonable response to the proceedings before the opposition division.

*Main request (patent as granted)*
*Added subject-matter (Article 100(c) EPC) - claim 13*

The specific features of this claim could be found on page 10, paragraph 1 and page 12, paragraph 3 of the application as filed.

While the functional feature of page 9, paragraph 5 relating to C3a/C5a was a key feature of antibody preparations according to one aspect of the invention, antibody preparations not having this feature were also disclosed in the application as filed. The skilled person would therefore not consider this feature to be mandatory in all antibody preparations described by the application.

In particular, both page 1, paragraph 1 and page 8, paragraph 2 described the antibody preparation of the present invention as being one which was capable of specific complement activation and substantially no unspecific complement activation.

Moreover, the skilled person was aware both that antibody preparations in this field were traditionally defined by the percentage of the different immunoglobulins present (see e.g. page 5, paragraph 1, final sentence and page 6, final paragraph of the application as filed) and that, as described on page 3, paragraph 2 and page 4, paragraph 2, aggregates of IgM had a high capacity to activate complement unspecifically. Therefore the skilled person, using common general knowledge and reading the present application as filed, would directly and unambiguously derive the combination of the teachings of page 10, paragraph 1, relating to the amounts of IgG, IgA and IgM, and page 12, paragraph 2, relating to levels of aggregates.

*Auxiliary request 1*
*Added subject-matter (Article 123(2) EPC) - claim 13*

The skilled person would combine claims 1 to 4, 11 and 12 and page 12, paragraphs 2 and 3 as filed, and would directly and unambiguously derive the subject-matter of claim 13 of the first auxiliary request. Further support could also be found in the fifth paragraph on page 9 and the first and third paragraphs on page 10 of the application as filed.

*Auxiliary request 2*
*Added subject-matter (Article 123(2) EPC) - claim 13*

The claim was based on claims 1 to 6, 10 and 11 as filed and the second paragraph on page 12 of the description as filed. The skilled person only had to turn to the description, page 12, second paragraph for the wording "of the total immunoglobulin content as determined by high performance size exclusion chromatography" which related to the feature of the percentage of aggregates as provided by claim 11 as filed. This paragraph taught the skilled person that the 1.5% value used in claim 11 referred to the percentage of the immunoglobulin content and that the amount of aggregates could be determined by high performance size exclusion chromatography. Therefore the skilled person did not have to make any unguided selections of subject-matter from the description in order to arrive at the subject-matter of claim 13.

*Claim 9*

The wording of claim 9 corresponded verbatim to claims 15 to 17 as filed. The appellant-opponent's arguments against this claim were an allegation of lack of clarity, which was not a ground for opposition under Article 100 EPC. Further, claim 9 was consistent with paragraph 4 of the application as filed and there was no contradiction between claims 9 and 10.

*Disclosure (Article 83 EPC)*

Regarding the features "*in vitro assay with human serum*" in claims 1, 3, 5 and 6 and "*90% of the antibodies in the preparation are biologically active, as determined by the Eur. Ph. 2.7.9* [D29] *Test for Fc*

*Function of Immunoglobulin*" in claim 14, the opposition division's reasoning in point 6 of the decision and the finding that the claimed subject-matter was sufficiently disclosed was correct. Regarding the objection to claim 11, the patent taught the nanometer filters that may be used in the nanofiltration step.

The description contained ample information enabling the skilled person to prepare the antibody compositions.

*Novelty (Article 54 EPC)*

The same standard had to be applied to the assessment of priority and of novelty, i.e. if the allegedly novelty-destroying subject-matter of D5b was entitled to priority the claimed subject-matter of the patent was also entitled to priority and D5b was not citable, and if the subject-matter of the patent was not entitled to priority the allegedly novelty-destroying subject-matter of D5b was not entitled to priority either and nor was D5b citable. This was supported by decision G 1/15 of the Enlarged Board of Appeal.

None of D10, D12, D15 or D19 disclosed an antibody preparation having the combination of features of the claims. In particular, none of these documents disclosed the C3a/C5a feature of claims 1 and 13.

Examples 9A and 9B of the patent showed that the antibody preparation of D17 did not meet the requirements of the C3a/C5a feature in the claim. Further, the appellant-opponent had provided no evidence that the antibody preparation of D18 met the requirements of the claims.

Accordingly, the subject-matter of the claims was novel.

*Inventive step (Article 56 EPC)*

The application as filed showed in Examples 9A and 9B that the antibody preparation of the invention was distinguished over two prior-art products, by the level of C3a and C5a generated in an *in vitro* assay. These prior-art products were Pentaglobin of EP 0 013 901 (EP equivalent of D17) and the IgM reference preparation according to EP 0 413 187 (EP equivalent of D6). The appellant-opponent acknowledged the findings of these data (see point 148 of the statement of grounds of appeal) but alleged that since the prior-art preparations of IgM were already toxicologically adequate they were not improved by providing the C3a/ C5a feature of the claims.

The appellant-opponent had alleged but had not shown that anti-complementary activity (ACA) measurement was predictive of the C3a and C5a generation levels.

C3a and C5a were anaphylatoxins. It was therefore desirable to avoid their non-specific generation *in vivo*, both because they might have effects that were not useful to the patient (and might be damaging) and because if components of the complement pathway were utilised non-specifically there might be less of these components available when they were needed in a specific response.

Accordingly, the antibody preparations of claims 1 and 13 could be regarded as improved products. The argument by the appellant-opponent that because toxicologically acceptable products (such as Pentaglobin) were known in

the art a product that generated less C3a/C5a non-specifically was not an improvement could not be accepted.

The application as filed provided *in vitro* data that showed that the antibody preparation of the invention generated less C3a and/or C5a than prior-art products *in vitro*. It was credible that this effect would also be seen *in vivo*. Example 10, referred to by the appellant-opponent, related to an experiment with a different purpose: it was not designed to show whether the antibody preparation of the invention was better or worse than Pentaglobin in relation to non-specific generation of C3a/C5a. Further, this example was performed in cynomolgus monkeys and not in humans. For these reasons this example did not undermine the *in vitro* results shown in Example 9 of the patent.

*Conciseness (Article 84 EPC) - claim 13*

The feature "*wherein the antibody preparation is prepared by a process which is capable of a more than* $3log_{10}$ *removal of non-enveloped viruses*" had a limiting effect on the claim. In particular, two antibody preparations both prepared from the same human plasma contaminated with non-enveloped virus, one of which was subjected to a process which was capable of a more than $3log_{10}$ removal and one of which was not, would be distinguished by this feature. Claim 13 further recited that the antibody preparation comprised less than 1.5% aggregates of 1200kDa or above "of the total immunoglobulin content as determined by high performance size exclusion chromatography", which was not recited in claim 7.

*Double patenting (Article 125 EPC)*

The appellant-opponent's allegations were not against proposed amended claims but against the claims as granted. Further, the appellant-opponent had not provided any reasoning to support its allegations of identical scope given that there were clear differences in the features recited in the claims referred to.

XIV. The appellant-opponent's arguments as far as relevant to the decision may be summarised as follows.

*Admission of documents*

Documents D45 and D46 as well as the corresponding data in documents D45a and D45b were filed at the earliest opportunity and before the final date for making written submissions set by the opposition division in its communication under Rule 116(1) EPC. Furthermore, the documents were *prima facie* relevant and should be taken into account regardless of when they were filed. Their filing anew with the statement of grounds of appeal was a direct reaction to the contested decision. The opposition division had failed to consider the *prima facie* relevance of the documents with respect to inventive step. Documents D45 and D46 were *prima facie* relevant in combination with the data in documents D45a and D45b, which revealed the corresponding value of the parameters in the prior art product.

Document D45 was filed at the earliest opportunity for the appellant-opponent to be able to provide evidence to confirm the relevance of this document as being prejudicial to maintenance of the patent in suit. Furthermore, the evidence was filed in direct response to a point addressed by the opposition division in the

preliminary opinion enclosed with the summons to oral proceedings dated 2 March 2017. In section 3 thereof, the opposition division stated that the features of C3a generation and C5a generation were "*technically meaningful and functionally limiting over the state of the art*". The opposition division did not address the objection that the parameters used in the claim were unusual and were not commonly used when describing similar preparations of the prior art.

Document D45 represented a clear and unambiguous protocol which a skilled person could follow in order to prepare an IgM containing immunoglobulin preparation. Documents D45a and D45b showed that the steps of this protocol could be replicated in order to arrive at an IgM composition falling within the scope of the claims of the patent (following the simple continuation step of document D46 which enhanced virus removal).

The antibody preparation of document D53 also *prima facie* had specific complement activating activity (adequate inactivation of human pathogenic virus) and was prepared by a process which was capable of more than $3\log_{10}$ removal of non-enveloped viruses (column 5, lines 35 to 49). Anti-complementary activity (ACA) in document D53 was measured in CH50/ml, as opposed to the more standard CH50/mg. This could be converted into CH50/mg in a straightforward manner. The preparations of D53 had low unspecific complement activation which was even better than the commercial product Pentaglobin (column 3, lines 17 to 22).

Document D55 was *prima facie* relevant because it was the only document cited which explicitly measured C3a generation induced by an IgM product. Figure 3 showed

that IgM preparations capable of generating the same amount of C3a as human serum were available at the priority date. This criterion was explicitly mentioned in claim 4 of the patent. Document D55 was therefore *prima facie* relevant at least with respect to inventive step.

*Main request (patent as granted)*
*Added subject-matter (Article 100(c) EPC) - claim 13*

Claim 13 represented an unallowable generalisation of specific embodiments of the invention (page 10, first paragraph; page 12, second paragraph; and claims 4 and 11 of the application as filed) because the functional limitation of the invention as originally disclosed, namely that the antibody preparation exhibited low levels of unspecific C3a or C5a activation, as required in claim 1, was not present in claim 13.

*Auxiliary request 1*
*Added subject-matter (Article 123(2) EPC) - claim 13*

The antibody preparation referred to on page 12, third paragraph of the application as filed was not a different composition from the antibody preparation generating substantially no unspecific C3a and/or C5a complement activation as stated in claim 1 of the application as filed. Page 12, third paragraph of the application as filed described an additional characterisation of the antibody preparation generating substantially no unspecific C3a and/or C5a complement activation described in claim 1 (or on page 9, fifth paragraph) of the application as filed, namely that the ACA was less than 1 CH50/mg protein (different test). It did not describe an alternative, different antibody preparation. Combining the disclosure of some

paragraphs on page 12 of the application as filed, while disregarding other paragraphs and the teaching of the claims, added subject-matter in contravention of Article 123(2) EPC.

*Auxiliary request 2*
*Added subject-matter (Article 123(2) EPC)*
*Claim 13*

In order to arrive at the subject-matter of claim 13, the skilled person had to firstly take the passage on page 9, penultimate paragraph of the application as filed. They then had to make a first selection of "at least 15% IgM" from the list of IgM concentrations in the first paragraph of page 10 of the application as filed. The skilled person then had to make a second selection of both "more than 5% IgA" and "more than 40% IgG" from these alternative embodiments disclosed on page 10, first paragraph. They then had to use the teaching on page 10, fourth paragraph. Finally, they had to turn to page 12, second paragraph to make a third selection of "less than 1.5% aggregates" from a list of aggregate sizes.

There had been multiple individual selections of preferred features from throughout the description (%IgG, %IgA, %IgM, % aggregates), in the absence of any combination of the features being indicated as preferred. Furthermore, no link was made between these different parameters in the description - they each represented a different property of the composition as a whole, and these were not interrelated.

In view of these multiple selections and combinations of features from throughout the description, claim 13 did not meet the requirements of Article 123(2) EPC.

*Claim 9*

Claim 9 was dependent on claim 1. This would suggest that the antibody preparation was prepared from both plasma and serum. It was not apparent how this would be possible.

This contradiction was further propagated, for example, in claim 10. As this claim was dependent on claim 9, it related to preparations obtained by preparing a plasma fraction from human serum. This was impossible. Thus the subject-matter of claim 9 and its dependent claims extended beyond the application as filed.

*Disclosure (Article 83 EPC)*
*"in vitro assay"*

Claims 1, 3, 5 and 6 referred to an "*in vitro assay*" which generated members of the complement cascade (C3a and/or C5a). In claim 1, it was stated that, as part of the assay, the antibody preparation was adjusted to an IgM concentration of 1.72 mg/ml. This had to refer to the antibody preparation stated in the opening line of the claim (i.e. the antibody preparation suitable for intravenous administration in humans comprising IgG, IgA and at least 5% IgM).

In claims 5 and 6 (dependent on claim 1), part (a) of each claim stated that a method step included "*adding an amount of the antibody preparation to 100 µl human serum to create a reaction mixture containing 1.72 mg/ml IgM...*". If the antibody preparation was adjusted to 1.72 mg/ml IgM initially, it was technically impossible to reliably create a reaction mixture containing 1.72 mg/ml IgM by adding this

preparation to 100 µl human serum, especially considering the variability of human serum.

It was impossible for the skilled person to carry out the method steps described in claims 5 and 6 because determining when to make the measurement represented an undue burden. The subject-matter of claim 1 was thus not sufficiently disclosed either.

*"90% of the antibodies in the preparation are biologically active"*

Claim 14 required that at least 90% of the antibodies in the preparation be "biologically active", as determined by the Eur. Ph. 2.7.9. test. However, as is evident from document D29, the Eur. Ph. 2.7.9. provided an index which gave a value relative to a specific reference preparation, and thus did not give an absolute value as required by the wording of the claim.

The Eur. Ph. 2.7.9. test (D29) contained numerous steps which relied on a subjective decision being taken. The skilled person thus had to make a number of arbitrary decisions which would necessarily have an impact on the eventual result.

The "biologically active" feature was not sufficiently disclosed, as one of its defining parameters could not be determined using the assay defined in the claim.

*"nanofiltration"*

Claim 11 was a product-by-process claim including a step of nanofiltration. A similar step of filtration was present in claim 15. Neither claim was limited to a particular size of nanofilter. A 20 nm filter used

would also catch IgM molecules as well as virus and thus not achieve the claimed product.

*Novelty (Article 54 EPC)*
*Document D5b*

The features of "*specific complement activating activity*" and "*in an in vitro assay … generates (i) substantially no C5a … and/or (ii) substantially no C3a*" found no basis in the priority application. Thus the skilled person could not derive these features directly and unambiguously from the priority application, and claim 1 lacked priority.

The fact that the methods described in document D5b were identical to that of the patent, the substantial overlap in the examples, and the fact that there were disclosures of the method providing low ACA, made it inevitable that the direct result of the disclosed processes in document D5b would anticipate the subject-matter of the claims, which were not entitled to priority.

*Documents D10, D12, D15 and D19*

Document D10 disclosed an IgM eluate which comprised IgG, IgA and 87.1% IgM (column 6, Table III), prepared from human blood plasma (claim 1), for therapeutic use, and thus comprising some level of activity, and suitable for intravenous administration (column 1, lines 16 to 17). This eluate was prepared by a process which comprised (Example 1) solvent-detergent viral inactivation treatment (column 3, lines 48 to 50) and nanometric filtration (column 4, lines 8 to 11). Both the solvent-detergent treatment and the nanometric

filtration were described as eliminating viruses (column 3, lines 19 to 20; claim 14).

D12 disclosed an antibody composition comprising IgG, IgA and at least 5% IgM (claims 1 and 2, page 11, second full paragraph), prepared from human blood plasma (page 3, first full paragraph), in which virus had been inactivated (page 4, second paragraph - treatment with p-propiolactone) and which did not activate complement (page 12), and disclosed the use of the composition in medicine and for bacterial infections (page 1, first paragraph).

As regards the anti-complementary activity, document D15 noted the inability of the IgM compositions to activate the complement cascade. On page 5, lines 2 to 5 it disclosed the requirement for complement activation to be considered minimal or negligible. Further, on page 10, lines 4 to 34, it disclosed the measurement of this minimal anti-complementary activity to be as low as 0.88 µg/ml.

Document D19, in particular, described the IgM solution as having extremely low anti-complementary activity (column 4, Table II; claim 1), thus anticipating at least claim 8 and implicitly passing the *in vitro* test as described in claims 5 and 6.

Documents D10, D12, D15 and D19 each disclosed all of the necessary features of the claims of the patent.

*Documents D17 and D18*

The values cited in the claim for C3a/C5a generation were inherent in a product already having an adequately low ACA value. The ACA assay and C3a/C5a ELISAs were

merely substitutes for one another, and a product having such a low ACA value would also have a C3a/C5a value which would fall within the scope of the claims. Moreover, the patent itself attested that the ACA assay and C3a/C5a ELISA were merely two ways of measuring the same thing, i.e. unspecific complement activation (see paragraphs [0039] and [0047] of the patent).

The subject-matter of claim 1 lacked novelty over the disclosure of each of documents D17 and D18.

*Inventive step (Article 56 EPC)*

The potential difference starting from documents D17 or D18 would be the same, namely that there was no explicit measurement of actual C3a and/or C5a generation.

The claimed feature of low C3a and/or C5a generation - whilst representing a strict linguistic difference over the prior art - did not actually impart any technical difference to the alleged invention of the patent.

C3a and C5a were each end products of the complement cascade. When the complement cascade was activated by intravenous immunoglobulin (IVig), formation of C3a and C5a resulted. In addition, another complement component, C5b-9, was produced. C5b-9 was the component of the complement cascade that resulted in the haemolysis of the red blood cells during the ACA assay. The amount of C3a and C5a generation by IVig measured by ELISA was proportional to the amount of C5b-9 generation as measured by the ACA assay.

Determination of the C3a and/or C5a levels did not impart any new information over an ACA read-out.

Moreover, an IVig product having a toxicologically acceptable ACA assay value would also have a C3a/C5a generation level that would not lead to any adverse side-effects or anaphylaxis.

While it might be accepted that Example 9 and Tables 10 and 11 showed that the IgM preparations of the patent displayed lower C5a and C3a generation than Pentaglobin, this difference did not equate to any biologically, toxicologically or clinically meaningful technical effect.

As there was no technical difference, there could also be no technical effect, and the objective technical problem had to be formulated as the mere provision of further information about the unspecific complement activating activity of prior-art IgM preparations (see appellant-opponent's statement of grounds of appeal, point 158). At most the objective technical problem could be seen as the provision of an alternative to the prior-art IgM preparations (statement during oral proceedings before the board).

It was not incumbent on the appellant-opponent to provide any specific motivation for the skilled person to measure the C3a and/or C5a generation of an IgM preparation. On the contrary, the burden lay with the appellant-patent proprietor to establish a credible technical effect resulting from such a measurement.

However, should the skilled person require any such motivation, they would find it in document D55, which explicitly measured C3a levels in a number of IgM preparations. This alone showed that it was possible to achieve the mere act of measuring C3a levels in an IgM preparation at the priority date.

Moreover, if the C3a level of known IgM preparations was already toxicologically adequate (i.e. the same or lower than human serum, as shown by document D55, Figure 3), the skilled person would have had no expectation that the measurement of an even lower C3a value would provide any further or additional toxicological benefit over and above that seen by the prior-art preparations.

Accordingly, the measurement of a C5a generation of less than 200 ng/ml and/or C3a generation of less than 6000 ng/ml did not provide a solution to a technical problem associated with the provision of further IgM preparations.

The subject-matter of the claims therefore lacked inventive step in view of document D17 or D18 as closest prior art, either alone or in combination with document D55.

*Conciseness (Article 84 EPC)*

The combined subject-matter of claims 1, 2, 3 and 7 (in view of their dependency on one another) was the same as that of amended claim 13. The feature "*wherein the antibody preparation is prepared by a process which is capable of a more than 3log$_{10}$ removal of non-enveloped viruses*" - as acknowledged by the opposition division - was not a technical, essential or limiting feature of claim 1.

The claims therefore lacked conciseness and did not meet the requirements of Article 84 EPC.

*Double patenting (Article 125 EPC)*

Document D4b was a patent granted to Biotest AG (i.e. the present appellant-patent proprietor). It had the same priority and filing date as the patent in suit, and described and claimed the same invention.

In particular, claim 15 of auxiliary request 2 and claim 8 of document D4b (as it depended on claims 1, 4 and 7) recited identical subject-matter, and hence were the same invention.

Furthermore, the subject-matter of the product claims was to all intents and purposes identical to the subject-matter of claim 10 of document D4b.

In the event that any of the claims of auxiliary request 2 and those of document D4b were deemed to have the same effective filing date, an issue under the prohibition of double patenting would arise.

XV. The appellant-patent proprietor requested that the decision under appeal be set aside and the patent be maintained as granted (main request), implying that the opposition be rejected, or, alternatively, that the patent be maintained in amended form on the basis of the set of claims of auxiliary request 1 filed on 27 June 2017, or in the version considered allowable by the opposition division (auxiliary request 2), implying that the appellant-opponent's appeal be dismissed, or, in the further alternative, based on one of the sets of claims of auxiliary request 3 filed on 27 June 2017, or of auxiliary requests 4 to 7, filed on 5 January 2018.

The appellant-patent proprietor further requested that none of documents D1b, D1c, D1d, D42 to D45, D45a,

D45b, D46 to D58 and D60 to D67 be admitted into the proceedings. In the event that any of these documents were admitted into the proceedings, it requested that the case be remitted to the opposition division. In the event that any of documents D45, D45a, D45b, D46, D47, D60, D66 and D67 were admitted into the proceedings it requested that document D59 also be admitted. The appellant-patent proprietor further requested that document D68 not be admitted into the proceedings, as well as document D69 and the associated new line of argument presented with the letter dated 24 May 2023.

XVI. The appellant-opponent requested that the decision under appeal be set aside and the patent be revoked *in toto*. The appellant-opponent further requested that documents D42 to D45, D45a, D45b, D46 to D58 and D60 to D69 be admitted into the proceedings. Document D59 should not be admitted into the proceedings.

## Reasons for the Decision

*Documents D1b, D1c, D1d, D42 to D44, D48 to D52, D54, D56 to D59*

1. Apart from in relation to the issue of admittance, the parties neither in writing nor during the oral proceedings referred to documents D1b, D1c, D1d, D42 to D44, D48 to D52, D54 and D56 to D58. In the letter dated 20 August 2019 the appellant-opponent briefly summarised the content of some of the documents relating to issues such as "vibrating agitators", "centrifugation", "virus activation", "pasteurisation" and "nanofiltration". None of these issues had to be considered by the board in order to arrive at the

present decision and the issue of admittance of the documents thus does not need to be addressed in the present reasons.

2. Document D59 filed by the appellant-patent proprietor in response to these documents therefore equally need not be addressed.

*Admittance of documents D45, D45a, D45b, D46, D47, D53, D55 (all filed during the opposition proceedings and not admitted by the opposition division) (Article 12(4) RPBA 2007)*

3. The appellant-opponent argued that the opposition division had not correctly analysed the content of these documents. However, a relevant issue in considering whether or not to hold inadmissible under Article 12(4) RPBA 2007 *inter alia* documents which were not admitted in opposition proceedings is whether the opposition division had exercised its discretion properly. The opposition division stated the reasons for not admitting these documents, namely that they had been filed "*extremely late*" (see decision, sheet 15, first paragraph), i.e. that they could and should have been filed earlier, and that the additional data provided in documents D45a and D45b did not show that they inevitably disclosed an antibody preparation according to the invention (see decision, sheets 15 to 18). They were thus not considered *prima facie* relevant.

4. The appellant-opponent argued that it had submitted documents D45 and D46 as soon as the corroborating experimental work D45a and D45b was at its disposal. However, there is no reason why the appellant-opponent could not have submitted documents D45 and D46 in a timely manner, and the supplementary experiments at a

later point in time. This argument was thus not considered convincing by the board.

5. D47 was filed in support of documents D45 and D46 and therefore the same reasoning applied.

6. With regard to documents D53 and D55 the board noted that no experimental evidence relating to these documents had been submitted, so the argument that they could not have been filed earlier because of the necessity of carrying out experiments cannot hold.

7. In summary, the board did not find any fault in the opposition division's exercising of its discretionary power and thus also holds inadmissible the documents pursuant to Article 12(4) RPBA 2007.

*Admittance of documents D60 to D67 (all filed with the statement of grounds of appeal of the appellant-opponent) (Article 12(4) RPBA 2007)*

8. These documents were filed for the first time with the appellant-opponent's statement of grounds of appeal.

9. Documents D60, D66 and D67 contain further details on the experiments presented in documents D45a, D45b and referring to documents D45 and D46. Since the latter documents do not form part of the appeal, documents D60, D66 and D67 were not relevant and were not admitted.

10. The content of documents D61, D63 and D64 was not addressed in the statement of grounds of appeal by the appellant-opponent (see point 3 therein), and the documents were therefore not considered relevant either and were not admitted.

11. Document D65 relates to antibody aggregate removal by hydroxyapatite chromatography which was not an issue which had to be considered by the board in reaching the present decision. The document was not admitted.

12. Document D62 was not admitted because it could and should have been submitted during opposition proceedings where the same issue, i.e. the question of C3a/C5a levels compared with an ACA assay, had already been discussed and was central to the case. This is apparent from the appellant-patent proprietor's reply to the notice of opposition (see pages 10 to 13) and from the preliminary opinion of the opposition division in the communication accompanying the summons to oral proceedings (see sheets 4 and 5).

*Admittance of documents D68 and D69 (filed with letters dated 20 August 2019 and 24 May 2023) (Article 13(1) RPBA 2007 and Article 13(2) RPBA 2020)*

13. D68 and D69 relate to a decision by an opposition division and a communication under Article 15(1) RPBA by a board of appeal of the EPO, respectively.

14. The appellant-opponent relied on these documents only in respect of process features such as "vibrating agitator" (see letter of 20 August 2019, pages 1 and 2 and letter of 24 May 2023, pages 1 and 2). As these aspects were not relevant to the decision, the documents were not admitted.

*Main request - claim 13*
*Added subject-matter (Article 100(c) EPC)*

15. The board agrees with the decision of the opposition division that the subject-matter of claim 13 extends beyond the content of the application as filed because it omits a feature originally disclosed as essential.

16. This feature "*wherein in an in vitro assay with human serum suitable to determine the ability of the antibody preparation to activate complement unspecifically the antibody preparation generates substantially no C5a and/or substantially no C3a*" is disclosed as an essential feature of the antibody preparation in paragraph 5 on page 9 of the application as filed. Paragraph 1 on page 10 and paragraph 2 on page 12, cited by the appellant-patent proprietor as disclosing the relevant features of claim 13, however, refer to "*the antibody preparation*", which the skilled person would consider to be the same antibody preparation as the one disclosed on page 9, paragraph 5. The feature disclosed on page 9 and the features on page 10 and 12 are thus disclosed in combination and cannot be separated without extending the subject-matter.

17. Also the broader features on page 1, paragraph 1 and page 8, paragraph 2, referred to by the appellant-patent proprietor, which relate to "*specific complement activating activity but low unspecific complement activation capacity*" or "*low anti-complementary activity*" are not present in claim 13.

18. Thus the subject-matter of claim 13 of the main request extends beyond the content of the application as filed and the ground for opposition pursuant to

Article 100(c) EPC prejudices maintenance of the patent as granted.

*Auxiliary request 1 - claim 13*
*Added subject-matter (Article 123(2) EPC)*

19. The claim contains the additional feature "*wherein the antibody preparation has specific complement activating activity, wherein the antibody preparation has an anti-complementary activity of less than 1.0 CH50/mg protein*". According to the appellant-patent proprietor, this feature was disclosed on page 12, paragraph 3 of the application as filed, and its combination with the passages on page 9, paragraph 5 and on page 10, paragraph 1 was directly and unambiguously derivable from the application as filed seen as a whole.

20. The passage on page 12, paragraph 3 reads "[a]*lternatively, or in addition the ability of the antibody preparation to generate substantially no unspecific complement activation can be defined as the anti-complementary activity of the preparation being less than 1.0 CH50/mg protein*" (highlighting added). It thus contains a reference to "*substantially no unspecific complement activity*" which is not present in claim 13. The passage on page 9, paragraph 5 defines the general features of the antibody preparation of the invention including that "*in an in vitro assay with human serum suitable to determine the ability of the antibody preparation to activate complement unspecifically the antibody preparation generates substantially no C5a and/or substantially no C3a*" (highlighting added). As the appellant-patent proprietor explained (see e.g. reply to the appellant-opponent's grounds of appeal, pages 14 to 15) it was common general knowledge that the CH50/mg protein value

in the ACA assay could not be equated to or transformed into C5a or C3a values. This had also been the understanding of the opposition division in its decision (see sheet 16, 10th to 6th lines from bottom), and is shared by the board. The skilled person, when reading the passage on page 12, paragraph 3, would therefore have concluded that the parameter of 1.0 CH50/mg protein could only be meant in addition to the *in vitro* assay in which substantially no C5a and/or substantially no C3a was generated, as defined on page 9, paragraph 5. This is also confirmed by claim 12 as filed, which refers to less than 1.0 CH50/mg protein and is dependent on claim 1, which refers to substantially no C5a and/or substantially no C3a in an *in vitro* assay.

21. Omitting the feature "*generates substantially no C5a and/or substantially no C3a*" therefore results in claimed subject-matter extending beyond the content of the application as filed (Article 123(2) EPC).

*Auxiliary request 2*
*Added subject-matter (Article 123(2) EPC)*

22. Compared with claim 13 of the main request and of auxiliary request 1, the claim is limited by the feature of "*no C5a and/or substantially no C3a*", which is an essential part of the disclosure in claim 1 as filed and on page 9, paragraph 5 as filed (see points above). The request therefore overcomes the objections in this regard.

23. The subject-matter of claim 13 is directly and unambiguously derivable from the subject-matter of claim 1 as filed combined with claim 2 as filed and preferred embodiments in claim 4 ("*at least 15% IgM*"),

claims 5 and 6 ("l*ess than 200 ng/ml C5a*", "*less than 6000 ng/ml C3*"), claim 11 ("*less than 1.5% aggregates*") and the preferred method for determining aggregates as disclosed on page 12, paragraph 2 as filed ("*determined by high performance size exclusion chromatography*"). In view of the hierarchical structure of the combination of features, the board does not agree with the appellant-opponent that the combination would result in the selection and combination of elements from different lists. The skilled person, rather, would have recognised that the application as filed disclosed the combination of preferred features in defining the antibody preparation.

24. The appellant-opponent further argued that the definition "*of the total immunoglobulin content*" in claim 13 compared with the disclosure on page 12, paragraph 2 ("*This refers to the % of the immunoglobulin content*"), extended the subject-matter beyond the content of the application as filed. The board does not agree, because the skilled person in the context of the application as filed would consider that the disclosure on page 12 equally related to the total immunoglobulin content as there is no indication in the application as filed to restrict the percentage to any subgroups of immunoglobulins. On the contrary, whenever a subgroup of immunoglobulins is meant it is specified as such.

25. The board further agrees with the decision of the opposition division that the subject-matter of claim 9 does not extend beyond the content of the application as filed. In the application as filed claims 15 and 16 already refer to "*prepared from human serum*" (while claim 1 refers to "*prepared from human plasma*"). The objection presented by the appellant-opponent that

there was a contradiction between "*prepared from human serum*" in claim 9 and "*prepared from human plasma*" in claim 1 therefore amounts to an objection of lack of clarity. However, it relates to subject-matter which was already present in the patent as granted (see granted claim 9). The alleged contradiction between claims 1 and 9 is thus not open to an assessment of an objection for lack of clarity, which is not a ground for opposition (see decision G 3/14, OJ EPO 2015, A102, order).

26. The subject-matter of the set of claims does not extend beyond the content of the application as filed (Article 123(2) EPC).

*Admittance of new submissions relating to the ELISA assay in the context of sufficiency of disclosure (Article 13(2) RPBA)*

27. During the oral proceedings the appellant-opponent argued that the ELISA assays disclosed in the patent (see e.g. paragraph [0042]) were not suitable to distinguish between specific and unspecific complement activation. The appellant-opponent referred to its statement of grounds of appeal, pages 31 and 33, with regard to sufficiency of disclosure, to which its new arguments represented only an "elaboration". The appellant-patent proprietor argued that these new submissions had not been made earlier in the proceedings and should not be admitted under Article 13(2) RPBA. They were surprising, and further consultation with the party's expert was required.

28. The board did not find any mention of the unsuitability of the disclosed assays to distinguish between specific and unspecific complement activation in writing by the appellant-opponent, and thus considered the new

submissions first made orally at the oral proceedings as an amendment to its appeal case. The question of admittance was thus governed by Article 13(2) RPBA. As no exceptional circumstances had been alleged, the board did not admit these new submissions into the proceedings.

*Disclosure (Article 83 EPC)*

29. The board has not been presented with serious doubts substantiated by verifiable facts that the invention as claimed in auxiliary request 2 can be carried out. In particular, the fact that only a single method for obtaining the claimed product was disclosed in the patent or the application as filed, as argued by the appellant-opponent, cannot be considered as evidence of insufficient disclosure. What does matter is whether the patent application provides the skilled person having common general knowledge with a sufficient and complete disclosure to carry out the claimed invention. In the case at hand, in which the claim relates to a product, it is crucial whether the skilled person was enabled to obtain the claimed product. This was not questioned by the appellant-opponent.

*"in vitro assay with human serum"*

30. With regard to claims 5 and 6, the appellant-opponent argued that if the IgM concentration was initially adjusted to 1.72 mg/ml as required in claim 1 it was not possible to add this preparation to 100 µl serum and still maintain the concentration of IgM.

31. The appellant-opponent has not substantiated why it considered the opposition division had erred in its decision in this regard. The board therefore sees no

reason to set aside the decision of the opposition division.

*"90% of the antibodies in the preparation are biologically active ..."*

32. With regard to claim 14, the appellant-opponent argued that the skilled person was not enabled to perform the required test.

33. The appellant-opponent has not substantiated why it considered the opposition division had erred in its decision in this regard. The board therefore sees no reason to set aside the decision of the opposition division.

*"nanofiltration"*

34. With regard to claim 11, the appellant-opponent argued that only nanofilters of a certain size would work, i.e. not also catch IgM molecules.

35. The board considers it within the ambit of routine adaptation and common general knowledge to choose a nanofilter of appropriate size.

36. The invention as claimed is disclosed in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art, in accordance with Article 83 EPC.

*Novelty (Article 54 EPC)*
*Document D5b*

37. The board fails to see how document D5b, which is a patent application filed on the same date as the

application on which the patent in suit was granted and claims priority from the same earlier application (D3), could anticipate the subject-matter of the present claims of auxiliary request 2. If, as the appellant-opponent argues, the present claims were not entitled to priority because they did not relate to the same subject-matter as the earlier application, the same would apply to document D5b, which claims priority from the same earlier application. The appellant-opponent also argued that the processes disclosed in D5b for which priority was validly claimed would necessarily lead to products falling under the scope of the present claims. However, those processes are disclosed in the application as filed as well as in the priority application, so the claims at least for the products resulting from said processes enjoy partial priority (see also decision G 1/15 of the Enlarged Board of Appeal, OJ EPO 2017, A82, point 4.3.3. of the Reasons).

*Documents D10, D12, D15 and D19*

38. The board agrees with the decision under appeal that these documents do not anticipate the subject-matter claimed in auxiliary request 2 because they do not disclose whether the antibody preparations have "*(i) substantially no C5a, such that the antibody preparation adjusted to an IgM concentration of 1.72 mg/ml generates less than 200 ng/ml C5a after 60 minutes of the assay; and/or (ii) substantially no C3a, such that the antibody preparation adjusted to an IgM concentration of 1.72 mg/ml generates less than 6000 ng/ml C3a after 60 minutes of the assay*". The argument of the appellant-opponent in this regard that this feature did not have a technical effect as it was not clinically or toxicologically relevant is not persuasive as it relates to questions of inventive step

rather than novelty. The further argument that the levels of this feature represented an "unusual parameter" while the feature itself could be considered a relevant parameter cannot convince the board either, because if a feature itself is considered relevant, merely determining its levels cannot represent an "unusual parameter".

*Document D17*

39. The board agrees with the decision under appeal that the claimed subject-matter is novel over document D17 because the product ("Pentaglobin") disclosed therein does not achieve the C3a/C5a levels required by claim 1. The appellant-opponent argued that the C3a/C5a levels required in the claim "*are inherent in a product already having an adequately low ACA value*" (see statement of grounds of appeal, point 128). The board does not agree, because the patent contains a direct comparison of the product disclosed in document D17 with the claimed product and shows a difference in the C3a/C5a levels (see comparative Examples 9A and 9B in the patent).

*Document D18*

40. The board fails to see why "the recited C3a/C5a values are inherent in a product already having an adequately low ACA value" as alleged by the appellant-opponent for document D18. The appellant-opponent points to the ACA levels being the same as for Pentaglobin. However, the latter, as shown in the patent, does not achieve the C3a/C5a levels required in the claim (see Examples 9A and 9B, Tables 10 and 11).

41. The claimed subject-matter is novel (Article 54 EPC).

*Inventive step (Article 56 EPC) - claim 1*
*Difference from the state of the art and objective technical problem*

42. Either of documents D17 or D18 can be taken to represent the closest prior art. For both documents the difference in the claimed subject-matter is the level of C3a/C5a generation in an *in vitro* assay. This is a clear and measurable technical difference and not a "*strict linguistic difference over the prior art* - [which] *does not actually impart any technical difference to the alleged invention*", as alleged by the appellant-opponent (see statement of grounds of appeal, point 141).

43. It is undisputed that the C3a/C5a levels of an antibody preparation could be measured and compared. It is further undisputed that C3a and C5a represent anaphylatoxins, the unspecific generation of which should be avoided (see patent, paragraphs [0010] to [0012]). It was common general knowledge for the skilled person in the field of pharmaceutical products at the effective date that the lowest level of toxic reaction products is desirable. The board therefore considers it irrelevant whether the claimed levels are below the "industry standard" or within a toxicologically acceptable range (see appellant-opponent's statement of grounds of appeal, point 151). What matters, rather, is whether an objective, measurable difference in these values is achieved by the claimed preparation. This has been accepted by the appellant-opponent (see statement of grounds of appeal, point 148: "*the IgM preparations of '682 display lower*

*C5a and C3a generation than Pentaglobin. While the Opponent-Appellant is willing to accept that this is the case, it is our view that this difference does not equate to any biologically, toxicologically or clinically meaningful technical effect*"). While the biological, toxicological and clinical effects of different levels of anaphylatoxins might be discussed and the view on this might also change over time as has been historically the case for many toxins, the achieved lower level of C3a and C5a as compared with Pentaglobin is a meaningful technical effect in view of the anaphylactic character of those compounds and the general cautious approach of a skilled person in the field of pharmacology.

44. The board therefore agrees with the objective technical problem defined by the opposition division as "*the provision of IgM enriched (human plasma) antibody preparations meeting the balance between high concentration of IgM and enhanced safety and tolerability in terms of unspecific activation of the terminal pathway of the complement system*". This problem has been solved by the claimed subject-matter as shown in Example 9, tables 10 and 11. The board does not agree with the appellant-opponent that the objective technical problem could be formulated as "*the mere provision of further information about the unspecific complement activating activity of prior art IgM preparations*" or at most as "*the provision of an alternative to the prior art IgM preparations*" (see statement of grounds of appeal, point 158). Such formulation would ignore the difference between the claimed subject-matter and the state of the art and its technical effect which is established by experimental evidence in the application as filed.

*Obviousness*

45. The appellant-opponent cited document D55 as having provided the skilled person with motivation to measure C3a levels in IgM preparations. As this document was not admitted by the board under Article 12(4) RPBA 2007, the appellant-opponent cannot rely on this document. Even if document D55 were taken into account, as already indicated in the decision under appeal, this document relates only to the measurement of C3a levels in IgM preparations, but does not provide any disclosure on how to obtain a preparation with the C3a/C5a levels required by the claim (see decision under appeal, sheet 17).

46. In the annex to the statement of grounds of appeal the appellant-opponent also referred to documents D20 to D25 with regard to inventive step. These documents, however, relate to aspects such as "vibrator", "vibrating stirrer", "rotating agitator", "UV irradiation" and "caprylic acid precipitation", i.e. issues which the board was not required to decide upon in reaching the present decision. Moreover, the appellant-opponent has not indicated in the annex to its statement of grounds of appeal in which these documents are cited how they would call into question the decision of the opposition division on inventive step. The board therefore sees no need to comment on these documents.

47. During the oral proceedings before the board, the appellant-opponent cited document D15, which allegedly disclosed "means to reduce unspecific anti-complement activity" by e.g. mild heat treatment. The appellant-opponent furthermore stated that low blood pressure was a side-effect caused by higher levels of C5a/C3a and

could be used as an indirect measure for the presence of these anaphylatoxins.

48. The appellant-patent proprietor questioned whether document D15 had been cited with regard to inventive step before. The appellant-opponent could not provide a relevant passage in its written submissions in this regard.

49. Neither document D15 nor the effect of low blood pressure was referred to by the appellant-opponent in the context of inventive step in its written submissions. During the oral proceedings the appellant-opponent did not request that the submissions relating to D15 in the context of inventive step be admitted into the proceedings nor did it rely on cogent reasons for late presentation of these submissions.

50. Even if document D15 were taken into account with regard to inventive step, this document does not disclose the characteristics of the claimed antibody preparation as generating "*(i) substantially no C5a, such that the antibody preparation adjusted to an IgM concentration of 1.72 mg/ml generates less than 200 ng/ml C5a after 60 minutes of the assay; and/or (ii) substantially no C3a, such that the antibody preparation adjusted to an IgM concentration of 1.72 mg/ml generates less than 6000 ng/ml C3a after 60 minutes of the assay*". Rather, document D15 discloses that the "*mild heat-treatment diminishes adverse side effects (hypotension)*" (see page 4, lines 24 to 27). This, however, cannot be equated with the specific characteristics required in claim 1. In conclusion, the appellant-opponent has not shown that the "*mild heat-treatment*" disclosed in document D15 would result in an antibody preparation as claimed.

51. In the absence of further evidence which would render the claimed antibody preparation obvious, the board finds that the state of the art did not provide the skilled person with the means to obtain an IgM preparation having the characteristics as defined in the claim.

*Claims 7, 10, 13 and 15*

52. As these claims depend on claim 1 or refer to the same distinguishing features as claim 1, the same reasoning as for claim 1 applies.

53. Thus the claimed subject-matter of auxiliary request 2 is inventive within the meaning of Article 56 EPC.

*Conciseness (Article 84 EPC)*

54. The appellant-opponent argued that the amendments to claim 13 resulted in it being directed to the same subject-matter as claims 1, 2, 3 and 7 in combination, thus leading to a lack of conciseness. The appellant-opponent further argued that the process of antibody preparation did not change the properties of the product. The board does not agree because claim 1 contains the additional features of "*wherein the antibody preparation is prepared by a process which is capable of a more than 3log$_{10}$ removal of non-enveloped viruses*" and of "*as determined by high performance size exclusion chromatography*", which had not been shown by the appellant-opponent to be without effect on the scope of the claim. In particular the feature of removal of non-enveloped virus, as also argued by the appellant-patent proprietor, changes the resulting product. The claimed subject-matter of claim 13 and

claims 1, 2 and 7 in combination is therefore not the same and the amendments comply with the requirements of Article 84 EPC.

*Double patenting (Article 125 EPC)*

55. It is well-established case law that the issue of double patenting can only arise with respect to claims directed to the same subject-matter (see also decision G 4/19, OJ EPO 2022, A24; Case Law of the Boards of Appeal, 10th edn. 2022, II.F.5.2 and II.F.5.3).

56. The board notes that none of the claims of auxiliary request 2 is identical to a claim of EP 2 560 691 (document D4b). The board does not agree with the appellant-opponent that claim 8 of EP 2 560 691 in its dependence on claims 1, 4 and 7 is directed to identical subject-matter to claim 15 of the present auxiliary request 2. In particular, it is noted that the present claim 15 relates to a "*method of producing an antibody preparation according to any preceding claim*". The antibody preparations defined in those preceding claims, however, have additional functional features which are not mentioned in the method of claim 8 of EP 2 560 691.

57. The issue of double patenting therefore does not arise.

**Order**

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

The appeals are dismissed.

The Registrar: The Chairwoman:

I. Aperribay M. Pregetter

Decision electronically authenticated