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**Datasheet for the decision  
of 25 January 2018**

**Case Number:** T 1603/14 - 3.3.07

**Application Number:** 08867937.8

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**Language of the proceedings:** EN

**Title of invention:**  
Counter-pressure filtration of proteins

**Patent Proprietor:**  
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Baxalta GmbH

**Opponent:**  
Almond-Martin, Carol

**Headword:**  
Counter-pressure filtration/BAXALTA

**Relevant legal provisions:**  
RPBA Art. 12(4)  
EPC Art. 54, 56

**Keyword:**

Late-filed requests - submitted with the statement of grounds of appeal

Late-filed evidence - submitted with the statement of grounds of appeal

Novelty - main request and auxiliary request 1 (no)

Inventive step - auxiliary requests (no)



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Case Number: T 1603/14 - 3.3.07

**D E C I S I O N**  
**of Technical Board of Appeal 3.3.07**  
**of 25 January 2018**

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**Decision under appeal:** **Interlocutory decision of the Opposition  
Division of the European Patent Office posted on  
16 May 2014 concerning maintenance of the  
European Patent No. 2242479 in amended form.**

**Composition of the Board:**

**Chairman**            J. Riolo  
**Members:**            A. Usuelli  
                             Y. Podbielski

## Summary of Facts and Submissions

- I. European patent No. 2 242 479, based on European patent application No. 08867937.8, was granted on the basis of twenty claims.

Independent claims 1 and 16 read as follows:

"1. A method of filtering a liquid protein mixture, the method comprising: providing a liquid mixture at a first pressure ( $P_1$ ), the liquid mixture comprising a carrier liquid, a protein at a first concentration ( $C_1$ ) relative to the carrier liquid, and a dispersed contaminant; passing the liquid mixture through a filter to form a filtrate at a second pressure ( $P_2$ ), the filtrate comprising the carrier liquid and the protein at a second concentration ( $C_2$ ) relative to the carrier liquid, wherein the filter is sized to remove at least a portion of the dispersed contaminant from the liquid mixture; and, applying a counter pressure to the filtrate to ensure that a pressure differential between the first and second pressures ( $P_1 - P_2$ ) is not more than 300 mbar".

"16. A method of filtering an aqueous protein mixture, the method comprising: providing an aqueous mixture at a first pressure ( $P_1$ ), the aqueous mixture comprising water and von Willebrand factor (vWF) at a first concentration ( $C_1$ ) relative to the water; passing the aqueous mixture through a porous membrane filter to form a filtrate at a second pressure ( $P_2$ ), the filtrate comprising the water and the vWF at a second concentration ( $C_2$ ) relative to the water, wherein the porous membrane filter comprises pores sized from 0.1  $\mu\text{m}$  to 0.5  $\mu\text{m}$ ; and, applying a counter pressure to the filtrate to ensure that a pressure differential

between the first and second pressures ( $P_1 - P_2$ ) is not more than 90 mbar".

- II. The patent was opposed on the grounds that its subject-matter lacked novelty and inventive step, it was not sufficiently disclosed and it extended beyond the content of the application as filed.

The following documents were among those cited during the first-instance proceedings:

D1: EP 1037923

D2: WO 2005/040214

D3: Vox sanguinis, (2004), 86, 100-104

D7: Lait, (2000), 80, 129-140

D12: Filtration in the biopharmaceutical industry, 1998, 373-379

- III. By an interlocutory decision posted on 16 May 2014, the opposition division decided that the patent in amended form met the requirements of the EPC. The decision was based on the patent as granted as main request and on five auxiliary requests filed on 7 October 2013 (auxiliary requests 1 and 2) and during the oral proceedings held on 9 December 2013 (auxiliary requests 3 to 5).

Claim 1 of auxiliary request 5 allowed by the opposition division differed from claim 16 of the patent as granted in that the following feature had been added at the end of the claim:

"...and wherein the first pressure  $P_1$  is at least 200 mbar gauge".

According to the decision under appeal:

- (a) The subject-matter of claim 1 of the patent as granted and of auxiliary requests 1 to 3 was anticipated *inter alia* by the disclosure in documents D2, D3 and D7.
- (b) The filtration method of auxiliary request 4 differed from the method disclosed in document D2 in the requirement that the first pressure was at least 200 mbar. In the absence of any unexpected technical effect arising from the selection of this specific value of pressure, the requirements of Article 56 EPC were not met.
- (c) Auxiliary request 5 met the requirements of the EPC. As to inventive step, the opposition division considered that the filtration method of claim 1 of this request was characterised *inter alia* by the indication that the pore size of the filter was between 0.1  $\mu\text{m}$  and 0.5  $\mu\text{m}$ . The teaching of D2 led away from using filters with pores of this size in combination with a low pressure, so that the subject-matter of auxiliary request 5 was deemed to be inventive.

IV. Appeals were filed against the decision of the opposition division by the patent proprietors (hereinafter: appellant-patent proprietors) and by the opponent (hereinafter: appellant-opponent).

V. With the statement setting out the grounds of appeal the appellant-patent proprietors submitted a main request and eleven auxiliary requests. A further auxiliary request (auxiliary request 12) was submitted on 16 February 2015. During the oral proceedings held

on 25 January 2018 the appellant-patent proprietors withdrew auxiliary request 3.

Claim 1 of the main request was identical to claim 1 of the patent as granted (see point I above).

Claim 1 of auxiliary request 1 differed from claim 1 of the main request in that the differential pressure ( $P_1 - P_2$ ) was not more than 90 mbar instead of not more than 300 mbar.

Claim 1 of auxiliary request 2 differed from claim 1 of auxiliary request 1 in that it specified that the protein was the von Willebrand factor (vWF).

Claim 1 of auxiliary request 4 differed from claim 1 of auxiliary request 2 in that the differential pressure ( $P_1 - P_2$ ) was not more than 50 mbar instead of not more than 90 mbar.

Claim 1 of auxiliary request 5 was identical to claim 16 of the patent as granted (see point I above).

Claim 1 of auxiliary requests 6 and 7 differed from claim 1 of auxiliary requests 1 and 2 respectively in that it specified that  $P_2$  was less than  $P_1$  and above ambient pressure.

Claim 1 of auxiliary request 8 differed from claim 1 of auxiliary request 1 in that the differential pressure ( $P_1 - P_2$ ) was set to 50 mbar or less instead of 90 mbar or less and in that it specified that  $P_2$  was less than  $P_1$  and above ambient pressure.

Claim 1 of auxiliary requests 9 and 10 differed from claim 1 of auxiliary requests 4 and 5 respectively in



that it specified that  $P_2$  was less than  $P_1$  and above ambient pressure.

Claim 1 of auxiliary request 11 was identical to claim 1 of the request that was considered by the opposition division to meet the requirements of the EPC (see point III above).

Claim 1 of auxiliary request 12 differed from claim 1 of auxiliary request 11 in that it specified that the aqueous mixture contained a dispersed contaminant and that the filter was sized to remove at least a portion of the contaminant from the mixture.

VI. With the statements setting out the grounds of appeal, the appellant-patent proprietors and the appellant-opponent submitted the following documents respectively:

D16: Expert declaration of Dr Liebminger

D19: Journal of Biological Chemistry, 281, (2006) 50, 38266-38275

VII. With the reply to the appeal of the patent-proprietors, the appellant-opponent submitted the following document:

D21: 2nd Declaration of Carol Almond-Martin

In the same letter, the appellant-opponent raised objections against the admissibility of some of the auxiliary requests filed by the appellant patent-proprietors with the statement setting out the grounds of appeal.

- VIII. The appellant-patent proprietors questioned the admissibility of documents D19 and D21 by letters of 16 February 2015 and 22 February 2016.
- IX. In a communication pursuant to Article 15(1) RPBA issued on 1 December 2017, the board expressed the view that document D7 anticipated the subject-matter of claim 1 of the main request and of auxiliary request 1. In relation to inventive step, it considered that document D3 was the closest prior art and that the method of filtration defined in the auxiliary requests differed from that of D3 in the application of a counter-pressure and in the lower value of the differential pressure. The board further observed that the prior art suggested carrying out the filtration process at low transmembrane pressure.
- X. For the course of the oral proceedings held on 25 January 2018, reference is made to the minutes.
- XI. The arguments of the appellant-patent proprietors, as far as they are relevant to the decision, can be summarised as follows:
- (a) Admissibility issues  
The filing of the auxiliary requests allowed the appellant-patent proprietors to properly react to the incorrect claim construction made by the opposition division. These requests were therefore admissible. Documents D19 and D21 were both late-filed and were not *prima facie* relevant. These documents were therefore not to be admitted into the appeal proceedings.
- (b) Novelty  
Document D7 was not novelty-destroying, since it failed to disclose the removal of a dispersed contaminant.

(c) Inventive step

The method of filtration defined in the requests on file differed from the method disclosed in D3 mainly in the application of a counter-pressure and in the reduced value of the transmembrane pressure. This had the effect of improving the filtration performance, in particular in terms of increasing the flow rate and filtration capacity. The application of very low transmembrane pressures made it possible to preserve the activity of shear sensitive proteins such as the vWF. As stated by Dr Liebinger (D16), very low transmembrane pressures in large scale filtration processes could not be technically achieved by conventional filtration technology, i.e. when only a head-pressure was applied. The technical problem was the provision of an improved process for the filtration of proteins such as vWF. D3 was silent as to the use of very low transmembrane pressure and did not provide any pointer towards the invention. Document D12 taught the use of low transmembrane pressures. However, this document merely provided a generic and theoretical teaching, without any reference to shear sensitive proteins such as vWF. Claim 1 of auxiliary request 5 specified the size of the pores of the filter. The use of filters with large pores had the effect of reducing damages to the protein. This was not suggested in D3.

XII. The arguments of the appellant-opponent, as far as they are relevant to the decision, can be summarised as follows:

(a) Admissibility issues

Auxiliary requests 2, 4 to 8 did not meet the criteria of being convergent. These requests were therefore not admissible.

(b) Novelty

The method of filtration of skimmed milk described in document D7 anticipated the subject-matter of at least the main request and auxiliary request 1.

(c) Inventive step

Document D3 described a process of filtration in which the transmembrane pressure applied was higher than that specified in the requests submitted by the appellant-patent proprietors. The skilled person knew that the transmembrane pressure was the driving force of a method of filtration. D12 explained that there was a decay of flow when working at high values of transmembrane pressures and suggested working at the lowest possible transmembrane pressure. This general principle applied to any methods of filtration, including closed systems in which two pressures above ambient pressure were applied. The experiments carried out by the appellant-patent proprietors were not suitable to show that the use of a counter-pressure resulted in some advantages. Indeed, the good results in terms of filtration performance were simply due to the application of very low transmembrane pressures. However, this effect was obvious in view of the teaching of D12. The mere fact of applying a counter-pressure could not justify the presence of an inventive step in the absence of any technical advantage due to the use of this technology that was part of the state of the art. The use of filters with large pore size as specified in auxiliary request 5 reflected the dimensions of the vWF multimers as disclosed in D19. Thus, this feature did not provide any inventive contribution to the claim.

XIII. The appellant-proprietors requested that the decision under appeal be set aside and that the patent be maintained on the basis of the main request or one of auxiliary requests 1, 2 and 4 to 11 filed on 26 September 2014 or auxiliary request 12 filed on 16 February 2015. It also requested that documents D19 and D21 not be admitted into the proceedings.

XIV. The appellant-opponent requested that the decision under appeal be set aside and the patent revoked. It also requested that auxiliary requests 2, 4 to 8, and 11 not be admitted into the proceedings.

## **Reasons for the Decision**

### Admissibility issues

1. The appellant-opponent raised objections to the admissibility of auxiliary requests 2, 4 to 8 and 11.

1.1 Auxiliary request 11 is identical to the request that was considered by the opposition division to meet the requirements of the EPC (auxiliary request 5 during the opposition proceedings). Accordingly, this request forms part of the basis of the appeal proceedings.

The opposition division considered that the filing of auxiliary request 5 during the oral proceedings was a legitimate attempt on the part of the patent-proprietors to overcome the problems of novelty and inventive step (paragraph 5.4 of the decision). In the board's view, this discretionary decision of the opposition division is not unreasonable, considering the fact that for the first time during the oral proceedings the division interpreted the feature "counter-pressure" as covering ambient pressure as

well. Hence, the board sees no reason to overrule the decision to admit auxiliary request 5 (now auxiliary request 11).

- 1.2 Auxiliary requests 2 and 4 to 8 were filed by the appellant-patent proprietors with the statement setting out the grounds of appeal.

As discussed in point 1.1.1 above, the opposition division changed its position on the meaning of the feature "counter-pressure" during the oral proceedings. This affected the conclusions of the opposition division on novelty and inventive step. The amendments introduced by the appellant-patent proprietors in auxiliary requests 2 and 4 to 8 represent, in the board's view, an attempt to address these conclusions. Accordingly, it cannot be affirmed that these requests should have been submitted at an earlier stage of the proceedings (Article 12(4) RPBA).

Hence, auxiliary requests 2 and 4 to 8 are admitted into the appeal proceedings.

2. Document D19 has been filed by the appellant-opponent with the statement setting out the grounds of appeal in response to some considerations made by the opposition division in relation to the size of the pores of the filter.

Document D21 has been filed by the appellant-opponent with the reply to the appeal of the patent-proprietors. This document addresses some of the criticisms expressed in the statement setting out the grounds of appeal by the appellant-patent proprietors against previous experiments made by the appellant-opponent.

The board sees no reason to consider that these documents should have been filed during the first-instance proceedings (Article 12(4) RPBA). Thus, documents D19 and D21 are admitted into the appeal proceedings.

Main request

3. Novelty

3.1 Document D7 describes a method of crossflow filtration for the separation of casein micelles from the soluble proteins of skimmed milk which involves the application of a "static" or "dynamic" counter-pressure (Introduction). The authors consider various operating procedures which are described in section 2.3 of the article. The experiments according to the "time" procedure (page 131, right column) are performed at constant flux or constant transmembrane pressure ( $\Delta P$ ). In paragraph 3.2.1, it is explained that experiments have been carried out at  $\Delta P$  of  $0.07 \times 10^5$  Pa, i.e. 70 mbar. Under this condition, the transmission of the protein  $\beta$ -lactoglobulin is stated to be high (page 132, right column, lines 30 to 37 and Figure 1). Hence, D7 discloses a method of filtration of a liquid mixture (milk) containing at least a protein ( $\beta$ -lactoglobulin) that can be recovered in the filtrate and a dispersed contaminant (casein micelles). The method involves the application of a counter-pressure that provides a  $\Delta P$  of 70 mbar.

3.2 The appellant-patent proprietors argue that the casein micelles cannot be regarded as a dispersed contaminant and that there is no evidence that the micelles are removed from the filtrate.

In the board's view, the skilled person would consider that in the context of a filtration process, a dispersed contaminant is a substance to be separated from the product that is to be isolated or purified by filtration. Thus, in a process of milk microfiltration for separating soluble proteins the casein micelles can be regarded as a dispersed contaminant. As to the absence of any evidence that the micelles are removed from the filtrate, the board observes that D7 clearly states that during milk microfiltration the casein micelles deposit on the membrane surface (Introduction). In the "conclusion" it is affirmed that the constant  $\Delta P$  mode is appropriate for conducting filtration runs since it prevents from sharp decrease of performance. Thus, in the board's view there is no reason to doubt that the deposition of the casein micelles on the filter indeed occurs.

Hence, the arguments of the appellant-patent proprietors are unconvincing.

- 3.3 It follows that D7 anticipates the subject-matter of claim 1 of the main request.

Auxiliary request 1

4. In the method of filtration defined in claim 1 of auxiliary request 1 the transmembrane pressure is no more than 90 mbar, whereas in the main request it is no more than 300 mbar.

As discussed above, document D7 discloses a method of filtration in which the transmembrane pressure is 70 mbar. Thus, auxiliary request 1 is also not allowable for lack of novelty over D7.



Auxiliary request 2

5. Inventive step

5.1 In contrast to the methods of filtration defined in the main request and in auxiliary request 1, the method of auxiliary request 2 is limited to the filtration of a specific protein, namely the von Willebrand factor (vWF).

5.2 Closest prior art

5.2.1 Document D3 is considered to represent the closest state of the art. The filtration method disclosed in this document is carried out under constant nitrogen pressure of  $200\pm 50$  mbar without counter-pressure. This implies that the transmembrane pressure in the filtration method of D3 equals the nitrogen pressure, i.e.  $200\pm 50$  mbar.

The method of claim 1 of auxiliary request 2 differs from the method of D3 in that a counter-pressure is applied and in the lower value of the transmembrane pressure, namely 90 mbar.

5.3 Technical problem

5.3.1 Examples 1 to 8 of the patent relate to processes of filtration of aqueous mixtures containing the vWF. The processes are carried out with the application of a counter-pressure (examples 5 to 8) or in the absence of it (examples 1 to 4). The data reported in Tables 2 to 4 indicate that the processes according to claim 1, carried out with a counter-pressure providing a transmembrane pressure below 4 mbar, provide better results in terms of filtration capacity, flow rate and

amount of vWF recovered than the processes in which no counter-pressure is applied and the transmembrane pressure is above 100 mbar.

- 5.3.2 In experimental report D16 the appellant-patent proprietors describe methods of counter-pressure filtrations of vWF solutions at variable values of transmembrane pressure. The results disclosed in Table 2 indicate that the reduction of the transmembrane pressure results in an increase of the filtered amount of protein. In the "Conclusion" section of D16 it is stated that the reduction of the transmembrane pressure determines an increase of filtration capacity and filtration performance.
- 5.3.3 The experiments of D16 demonstrate, in the board's view, the beneficial effects of working with low transmembrane pressures. Indeed, the methods disclosed in this report differ from each other only in the value of the transmembrane pressure, and the results clearly show an improvement in filtration performance with the decrease of this pressure.
- 5.3.4 On the other hand, the board considers that there is no evidence of any improvement or advantage due the application of a counter-pressure.

In this regard it is noted that in the experiments of D16 a counter-pressure is always applied, so that no comparison can be made between processes carried out with counter-pressure or without it.

As to examples 1 to 8 of the patent, the board notes that in the filtrations in which the counter-pressure is applied (examples 5 to 8), the values of transmembrane pressures are very low (below 4 mbar),

whereas when no counter-pressure is applied (examples 1 to 4), the values of transmembrane pressures are high (at least 100 mbar). Thus, having regard to this important difference in the transmembrane pressure, no conclusion can be drawn as to the effects of the counter-pressure by comparing the filtration data of examples 1 to 4 and 5 to 8.

5.3.5 Summing up, on the basis of D16 it can be concluded that reducing the transmembrane pressure provides an increase in filtration performance (see points 5.3.2 and 5.3.3 above). The technical problem can therefore be formulated as the provision of an improved process for the filtration of vWF, wherein the improvement resides in an improvement of the filtration parameters such as the filtered amount of protein and filtration capacity.

5.4 Obviousness

5.4.1 D12 (page 378, paragraph 3.5) explains that elevations in the level of transmembrane pressure may increasingly promote the rate of filter blockage and hence decrease throughput. In the same paragraph, it is affirmed that the lowest possible transmembrane pressure is generally preferred because throughput volume and filter longevity are usually greater, which improves filtration economics. Furthermore, the lower rates of flow are compensated for by the greater duration of flow.

The same teaching is provided for instance by document D1, which affirms that the filtration yields are considerably improved when the transmembrane pressure during the filtration is lowered to very low values (paragraph [0021]).

- 5.4.2 The skilled person confronted with the problem of improving the filtration parameters of the process disclosed in D3 would therefore find in the prior art a clear indication to reduce the transmembrane pressure at the lowest possible value.

As it can be derived from D12 (paragraph 3 on page 375), low values of transmembrane pressure can be achieved in open systems, i.e. in systems wherein no counter-pressure is applied, by the application of a weak head pressure, and, in closed systems, i.e. in systems wherein a counter pressure is applied, by regulating the head pressure ( $P_1$ ) and the counter-pressure ( $P_2$ ) in such a way as to obtain a low value of transmembrane pressure ( $P_1 - P_2$ ).

In the same paragraph of D12 it is affirmed that the filter is affected only by the transmembrane pressure.

- 5.4.3 Thus, applying a counter-pressure and regulating the two pressures is just one of the two alternative ways for achieving a low value of transmembrane pressure. As explained in D12, this value is the sole factor that affects the performance of the filtration.

Since methods of filtration involving the use of counter-pressures are known in the art (see paragraph 3 of D12 and Figure 1), the mere fact of applying this technology does not involve any inventive merit in the absence of any unexpected advantage.

Thus, none of the modifications over the method of D3, namely the reduction of the transmembrane pressure and the application of a counter-pressure, justify the presence of an inventive step.

5.4.4 As regards the appellant-patent proprietors' argument that in large-scale processes low transmembrane pressures can be achieved only by the application of a counter-pressure, it is noted that the claims are not limited to large-scale processes.

Furthermore, this advantage is a feature of the counter-pressure technology as such, i.e. it is not linked to the fact that this technology has been applied to the filtration of the vWF. However, methods of counter-pressure filtrations are part of the state of the art. Thus, a feature of the counter-pressure technology as such cannot support the presence of an inventive step for the subject-matter of the present claim.

5.4.5 The argument that a skilled person would not apply a counter-pressure during the filtration of shear sensitive proteins is also unconvincing. Indeed, there are no documents suggesting that the application of a counter-pressure during the filtration would compromise the integrity of the vWF.

5.5 In the light of the above considerations, the board concludes that claim 1 of auxiliary request 2 does not fulfil the requirements of Article 56 EPC.

#### Auxiliary request 4

6. In claim 1 of auxiliary request 4, the transmembrane pressure ( $P_1 - P_2$ ) is reduced to not more than 50 mbar.

6.1 As explained in point 5.4.1 above, D12 suggests the application of the lowest possible transmembrane pressure. Thus, claim 1 of auxiliary request 4 is not

inventive for the same reasons as set out in relation to auxiliary request 2.

Auxiliary request 5

- 7. Claim 1 of auxiliary request 5 specifies that the membrane filter comprises pores sized from 0.1  $\mu\text{m}$  to 0.5  $\mu\text{m}$ .
- 7.1 In the filter used for the filtration process of D3, the pores have a size of 0.035 $\mu\text{m}$  (page 101, right column). According to D19 (abstract) the ellipsoid dimensions of the multimers of vWF are 175 x 28 nm (i.e. 0.175 x 0.028  $\mu\text{m}$ ).

In the board's view, the skilled person concerned with the problem of filtering an aqueous mixture containing a protein would obviously consider using a filter in which the size of the pores is greater than the size of the protein that must pass through the filter. He would furthermore expect that using a filter with pores of large size would reduce the chance of blocking the filter and of damaging the protein. Thus, the advantages claimed by the appellant-patent proprietors do not support the presence of inventive activity.

- 7.2 Thus, claim 1 of auxiliary request 5 does not fulfil the requirements of Article 56 EPC.

Auxiliary requests 6 and 7

- 8. In claim 1 of these requests it is specified that the counter-pressure  $P_2$  is less than the first pressure  $P_1$  and above ambient pressure. The claims of the two requests differ from each other in that in one case the method concerns the filtration of any protein

(auxiliary request 6), whereas in the other case it is limited to the filtration of the vWF (auxiliary request 7).

8.1 Since vWF is a protein, the general approach on inventive step followed for auxiliary request 2 applies also to the subject-matter of auxiliary request 6.

8.2 Concerning the specification that the second pressure  $P_2$  is less than the first pressure  $P_1$  and above ambient pressure, the appellant-patent proprietors explained that this feature was introduced as a precautionary measure in order to clarify that the counter-pressure is not the ambient pressure. It did not submit any argument as to the relevance of this feature in the assessment of inventive step.

8.3 The board confirms that this feature does not provide any inventive contribution to the subject-matter of the claim. As discussed above (see points 5.4.1 and 5.4.2), D12 suggests using low values of transmembrane pressure and explains that the performance of the filtration is affected only by this pressure. Low values of transmembrane pressure can also be obtained using a counter-pressure which is above the ambient pressure, provided that the first pressure  $P_1$  (head pressure) is regulated accordingly.

Thus, auxiliary requests 6 and 7 do not fulfil the requirements of Article 56 EPC.

#### Auxiliary request 8

9. In claim 1 of this request it is specified that the differential pressure is not more than 50 mbar (feature

(a)) and that  $P_2$  is less than  $P_1$  and above ambient pressure (feature (b)).

Furthermore, the method concerns the filtration of any protein.

- 9.1 Features (a) and (b) do not provide any inventive contribution, for the reasons explained in points 6.1, 8.2 and 8.3 above. Furthermore, as discussed in point 8.1 above, vWF is a protein. Thus, the general approach to inventive step starting from D3 as the closest prior art (see auxiliary request 2) also applies to the subject-matter of auxiliary request 8.

Hence, auxiliary request 8 does not fulfil the requirements of Article 56 EPC.

Auxiliary requests 9 and 10

10. The methods of filtration defined in claim 1 of these requests differ from the methods of claim 1 of auxiliary requests 4 and 5 respectively in specifying that  $P_2$  was less than  $P_1$  and above ambient pressure.
- 10.1 As explained with regard to auxiliary requests 6 and 7 (see point 8.2 and 8.3), this feature does not provide any inventive contribution to the subject-matter of the claim.

Hence, the subject-matter of claim 1 of auxiliary requests 9 and 10 does not comply with the requirements of Article 56 EPC.



Auxiliary request 11

11. Auxiliary request 11 is the request considered by the opposition division to comply with the requirements of the convention.

Claim 1 of this requests differs from claim 1 of auxiliary request 5 in that it indicates that  $P_1$  is at least 200 mbar gauge.

- 11.1 The appellant-patent proprietors did not present any argument as to the relevance of this feature in the assessment of inventive step.

The board observes that in D3 too,  $P_1$ , i.e. the head pressure, is at least 200 mbar (page 102, line 2 of left-hand column).

Furthermore, as discussed above in relation to auxiliary request 2, the process of filtration is affected by the transmembrane pressure only. This can in principle be achieved with any value of head-pressure ( $P_1$ ), provided that the counter-pressure is adapted accordingly. The transmembrane pressure defined in claim 1 of auxiliary request 11 is not more than 90 mbar. The selection of this range of transmembrane pressure does not involve any inventive activity, as explained in relation to auxiliary request 2.

Hence, auxiliary request 11 does not fulfil the requirements of Article 56 EPC.

Auxiliary request 12

12. Claim 1 of this request differs from claim 1 of auxiliary request 11 in that it indicates that the aqueous protein mixture contains a dispersed contaminant and that the filter is sized to remove at least a portion of the contaminant from the mixture.
- 12.1 This request was filed by the appellant-patent proprietors in reply to objections under Article 123(2) EPC raised by the appellant-opponent against auxiliary request 11. The appellant-patent proprietors did not submit any argument as to the relevance of the features introduced in auxiliary request 12 for the assessment of inventive step.
- 12.2 The main purpose of a process of filtration is to remove contaminants from a product to be purified. This also occurs in the process disclosed in D3 (see Table 1 and page 102, first paragraph of "Results and discussion"). Hence, the mere fact of specifying that the filter is sized to remove at least a portion of the contaminant from the mixture does not provide any inventive contribution to the subject-matter of the claim.

Hence, auxiliary request 12 does not fulfil the requirements of Article 56 EPC.

**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:



R. Schumacher

J. Riolo

Decision electronically authenticated