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**Datasheet for the decision
of 18 November 2024**

Case Number: T 1108/22 - 3.3.04

Application Number: 10740823.9

Publication Number: 2462158

IPC: C07K16/06, C07K1/18, C07K1/34,
C07K1/36

Language of the proceedings: EN

Title of invention:
Method to improve virus removal in protein purification

Patent Proprietor:
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Headword:

Method/ROCHE

Relevant legal provisions:

EPC Art. 84
RPBA 2020 Art. 11, 12(4), 12(6)

Keyword:

Main request - clarity in opposition appeal proceedings -
claims - clarity (no)
Auxiliary request - admitted (yes) - claims - clarity (yes)
Remittal - special reasons for remittal

Decisions cited:

G 0002/88, G 0003/14, T 0219/83, T 2053/13, T 0081/14,
T 1702/15, T 1471/16

Catchword:



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Case Number: T 1108/22 - 3.3.04

D E C I S I O N
of Technical Board of Appeal 3.3.04
of 18 November 2024

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Decision under appeal: **Decision of the Opposition Division of the
European Patent Office posted on 25 February
2022 revoking European patent No. 2462158
pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

Chairman A. Chakravarty
Members: D. Luis Alves
 A. Bacchin

Summary of Facts and Submissions

- I. The patent proprietor (appellant) filed an appeal against the decision of the opposition division to revoke the patent 2 462 158, entitled "*Method to improve virus removal in protein purification*".
- II. Eleven parties had filed oppositions, invoking grounds for opposition under Article 100(a) EPC, lack of novelty (Article 54 EPC) and lack of inventive step (Article 56 EPC), and under Article 100(b) and (c) EPC.
- III. In its decision, the opposition division considered a main claim request and eight auxiliary claim requests. It held that none of these claim requests complied with the requirements of clarity under Article 84 EPC.
- IV. With the statement setting out the grounds of appeal, the appellant filed sets of claims of a main request and 22 auxiliary requests. The main request and auxiliary requests 1, 2, 8 and 20 to 22 are identical to the main request and auxiliary requests 1, 2, 8, 3, 4 and 6, respectively, considered by the opposition division. The other requests are newly filed on appeal. Furthermore, the appellant filed documents D90 and D91.
- V. Opponent 2 (respondent II) and opponent 3 (respondent III) submitted replies to the statement setting out the grounds of appeal. Respondent II filed two annexes with its reply. Opponents 1 and 4 to 11 (respondents I and IV to XI, respectively) did not make any substantive submissions in the appeal proceedings.

- VI. With a letter dated 19 July 2023, the appellant made further submissions.
- VII. The board appointed oral proceedings and in a communication pursuant to Article 15(1) RPBA, informed the parties of its preliminary opinion *inter alia*, that in case the appeal were to be allowed, it was inclined to remit the case to the opposition division for assessment of the remaining grounds for opposition.
- VIII. Respondents II and III filed further arguments with the letters dated 25 October 2024 and 1 October 2024, respectively.

Respondents I and IV to XI informed the board that they would not be attending the oral proceedings.

- IX. The oral proceedings took place in the presence of the appellant and respondents II and III and in the absence of the respondents I and IV to XI, as previously announced. At the oral proceedings, the appellant withdrew the main request and auxiliary requests 1 and 3. Previous auxiliary request 2 became the main request. At the end of the oral proceedings, the Chair announced the board's decision.
- X. Claims 1 and 11 of the **main request** (filed as auxiliary request 2 with the statement of grounds of appeal) read as follows:

"1. A method of improving the filtration capacity of a virus filter during protein purification,

consisting of subjecting a composition comprising a protein to be purified to a cation exchange step and an

endotoxin removal step, in either order, prior to passing through said virus filter,

wherein the protein to be purified is a therapeutic monoclonal antibody or a fragment thereof,

wherein the composition comprising the protein to be purified is an ion exchange chromatography pool,

wherein the virus filter is a parvovirus filter,

and wherein in the cation exchange step the composition is processed over a cation exchange membrane adsorber and in the endotoxin removal step the composition is processed over an endotoxin removal membrane adsorber."

"11. Use of a prefiltration train for improving the filtration capacity of a parvovirus filter during protein purification,

wherein the protein is a therapeutic monoclonal antibody or fragment thereof

said prefiltration train consisting of a cation exchange medium membrane adsorber and an endotoxin removal medium membrane adsorber

wherein said use comprises processing an ion exchange chromatography pool over the prefiltration train and filtering the subsequent pool with said parvovirus filter."

Claim 1 of **auxiliary request 4** is the same as as claim 1 of the main request. Claim 11 has been deleted in auxiliary request 4.

XI. The appellant's arguments, as far as relevant to this decision, are summarised as follows:

Main request (filed as auxiliary request 2 with the statement of grounds of appeal)

Clarity (Article 84 EPC)

Claim 1

Which features may be examined for compliance with the requirements of Article 84 EPC

In view of decision G 3/14, the expression "A method of improving ... during protein filtration, consisting of" could not be examined for clarity. Indeed, all the alleged ambiguities had been present in the claims as granted, despite the argument that they were caused by the introduction of the feature "ion exchange chromatography pool" (IEX pool) into claim 1. For example, the question of whether "consisting of" meant that cation exchange chromatography (CEX) and endotoxin removal (ER) alone were responsible for improving the filtration capacity, and whether no additional steps could be included in the method, applied likewise to claim 1 as granted.

Claim interpretation

The claim was to be interpreted with a mind willing to understand. The opposition division's interpretation of the claim was not technically sensible and failed to take the wording of the claim into account:

The claim wording included a comma preceding the expression "consisting of". This implied that "consisting of" applied to the method of improving the

filtration capacity of the filter, rather than to the method of protein purification.

A technically sensible interpretation of the claim also led to the conclusion that the method of protein purification did not consist of two steps only. The skilled person was aware of the use of filtration steps to increase the filtration capacity of a parvovirus filter. The technical context provided in the patent description should be taken into account (see paragraphs [0125 to 127]) and this did not support a different interpretation of the claim.

In summary, the claim was directed to a method that was not limited to the steps responsible for "improving the filtration capacity". Generating the IEX pool was included in the purification method. According to the wording of the claim, the IEX pool was necessarily an intermediate in the purification process. Therefore, the skilled person would have no doubt about which methods fell within the scope of the claim.

"IEX pool"

The opposition division concluded that the requirements for product-by-process definitions also applied to this feature. However, this was not the case, since claim 1 related to a method. The contested feature was a process feature in a process claim. The "IEX pool" was an intermediate, not a starting material. This feature served to further define the stage of protein purification at which the pre-filtration steps were taking place.

A skilled person would not refer to "IEX pool" unless it resulted from IEX. The opponents provided no evidence that "IEX pool" could mean anything else.

Claim 1 was directed to a method, unlike the claims considered by the boards in the decisions cited by the opposition division and the opponents, which were directed to the use of a product to achieve a technical effect. Thus, the case law concerning the product-by-process definition of a product was not to be applied here. Hence, the requirement that "IEX" impart identifiable properties to the "IEX pool" did not apply here. Instead, the requirement not to unduly limit the claim applied (see T 81/14 and T 1471/16). In T 1471/16, the term "harvested" in the expression "harvested cell culture fluid", which also defined a feature by reference to a process, had been considered clear (see point 10 of the reasons).

"therapeutic antibody"

The term "therapeutic" was clear. The expression "therapeutic antibody" was used, for example, in documents D17, D26 and D35 (see the titles). Moreover, claim 1 was not directed to a therapeutic antibody *per se*. This feature merely defined the method's field of application.

In any case, the argument that therapeutic uses change over time was a new line of attack. It should not be admitted into the appeal proceedings.

Even if the line of attack were admitted, the factual situation in decision T 1702/15 was different to that in the present case.

Claim 11

The amendment to claim 11 relative to claim 15 as granted involved changing from a product to a use claim. However, a change in claim category did not *per se* allow for the claim to be examined for clarity in view of decision G 3/14 (see decisions T 326/02, T 384/16 and T 22/09).

The term "improving" was already present in claim 15 as granted. Also the purpose was present in claim 15 as granted. The fact that it now defined the purpose of the use, whereas in claim 15 as granted it defined the suitability of the product, did not on its own introduce a lack of clarity. A definition of suitability in claim 15 as granted could not simply have been disregarded. Therefore, any lack of clarity did not arise from the amendment.

Auxiliary request 4 (filed as auxiliary request 4 with the statement of grounds of appeal)

Admittance into the appeal proceedings

In this claim request, claim 11, which had been objected to for lack of clarity, had been deleted. There were multiple opponents and a multitude of objections. The fallback positions filed during opposition proceedings had been directed at these objections.

At oral proceedings, the opposition division held that claims 1 and 13 (claim 11 in the present main request) were not clear. Therefore, filing this auxiliary request at oral proceedings before the opposition division would not have been appropriate since it merely would delete claim 13 but would still leave

unamended claim 1, that was also considered not clear. Instead, an auxiliary request was filed with an amended claim 1.

Deleting claim 11 did not introduce complexity, nor did it raise new issues with respect to the remaining claims. Admittance of this request was also in the interest of procedural economy, since it contained the deletion of a claim objected to and thus eliminated a point at dispute.

*Remittal of the case to the opposition division
(Article 11 RPBA)*

The opposition division had not decided on the requirements of Article 123(2) and (3) EPC. Since the primary object of the appeal proceedings was to review the decision under appeal, the case should be remitted also for a decision on this issue (see T 315/21, point 5 of the reasons).

The eleven opponents had raised many and complex objections under Article 123(2) EPC. Many of these had not been discussed before the opposition division and the opposition division's decision did not address any of the objections under Article 123(2) EPC. The board's communication pursuant to Article 15(1) RPBA did not address Article 123(2) EPC either. Even if some aspects of clarity and added subject-matter might be interlinked, this applied only to a limited number of the objections raised.

The number of oppositions was not a reason against remittal of the case and did not play a role under Article 11 RPBA, as illustrated in decision T 99/13, which also related to a case with eleven opponents. The board in that decision remitted the case to the

opposition decision after deciding on the sole issue in the decision under appeal, in the case Article 123(2) EPC.

XII. The respondents' arguments, as far as relevant to this decision, are summarised as follows:

Main request (filed as auxiliary request 2 with the statement of grounds of appeal)

Clarity (Article 84 EPC)

Claim 1

Which features may be examined for compliance with the requirements of Article 84 EPC

The amendment "ion exchange chromatography pool" introduced a lack of clarity. It was unclear whether the steps responsible for "improving the filtration capacity" were limited to cation exchange chromatography and endotoxin removal, as implied by the wording "consisting of" or whether additional steps of IEX also contributed to the improvement. The amendment implied an IEX step, but it was unclear whether that method step was part of the claimed method. This question did not arise in claim 1 as granted. Therefore, this amendment could be examined for compliance with the requirements of Article 84 EPC.

Clarity of "IEX pool" and claim interpretation

The expression "IEX pool" did not define an active IEX step, but rather a product. Even though the term was used in a method claim, the expression still referred to a product. According to G 2/88 (reasons 2.2), claims could comprise both features relating to physical

activities and features relating to physical entities. Thus, the format of claim 1 as a method claim did not preclude that certain features be defined by reference to product features. "IEX pool" was such a product feature, defined in terms of product-by-process.

The case law on product-by-process applied also to method claims (see T 81/14, T 2053/13 and Case Law of the Boards of Appeal of the EPO, 10th ed., 2022 (CLBA), II.A.7.4). It required that the skilled person be able to determine which features were imparted to the product by the process by which it was defined (CLBA, II.A. 7.1, fourth paragraph). Even if defined by reference to a process, a product had to be interpreted in absolute sense, i.e. independently from the process (see CLBA, II.A.7.2 and T 219/83). Thus, the feature "IEX pool" was to be assessed for clarity on its own, to assess whether its characteristics were clear.

The claims must be clear in themselves (see CLBA, II.A. 3.1). Furthermore, since the essential features of the claimed method should be clear and "IEX pool" was an essential feature of claim 1, it needed to be clear so that novelty of the claimed method could be assessed.

In relation to the meaning of the terms, it was established case law that the features in a claim should be given the broadest technically sensible interpretation possible. Thus, "IEX pool" was to be interpreted as defining a product. It was not illogical to interpret the claimed method as starting with an "IEX pool" (see CLBA, II.A.6.1). The claim could have been worded to define an active IEX step, but it was not. Thus, "IEX pool" was not an intermediate material, but rather the starting material for the method defined

in claim 1, since no method step was defined prior to that.

The product "IEX pool" was not limited to compositions resulting from IEX. However, it was not possible for the skilled person to determine whether a given product resulted from IEX or from other method steps that also removed charged species. The application disclosed that the same purification could be achieved with different methods such as CEX and hydrophobic interaction chromatography (HIC) (see page 26, lines 14 to 15). Furthermore, from the patent it was clear that the conditions used for carrying out CEX impacted the resulting composition (see paragraph [0134]). Therefore, the feature "IEX pool" was not clear. In decision T 1471/16, cited by the appellant as example of a product feature defined with reference to a process, clarity was not the issue under consideration. Moreover, the only reason the product was considered supported was that the claim included structural definitions.

Moreover, the skilled person could not establish whether the claim encompassed a three-step method. Therefore, they could not determine whether they were working inside or outside the claimed scope. The IEX step was not clearly assigned to the protein purification method either, as it was not mentioned in the first line of the claim.

"therapeutic antibody"

The term "therapeutic" was used to define a product mentioned in the claim and should therefore be clear. The fact that this term was used in scientific

literature was irrelevant, as the requirements of Article 84 EPC did not apply to scientific literature. Decision T 305/13 cited by the appellant did not assist their case because the claim in question included structural features.

The therapeutic value of many antibodies might only be recognised at a later point in time, so the assessment of what was encompassed by the claim was time-dependent (see T 1702/15). This was not a new line of attack as alleged by the appellant, as it still related to clarity.

Furthermore, the appellant's arguments did not apply to "fragments".

Claim 11

The expression "Use of a prefiltration train for improving the filtration capacity of a parvovirus filter" could be examined for clarity because of the change in claim category. Moreover, the claim could be examined for clarity in respect of the new steps defined by the wording "wherein said use...".

The appellant cited decisions T 326/16 and T 22/09 to support its argument that a change in claim category did not *per se* allow for the claim to be examined for clarity in view of decision G 3/14. However, decision T 326/16 related to a use claim which defined a relationship between structural features of a product and its function. It did not define a use for achieving an effect as in present claim 11. Indeed claim 15 as granted was not directed to a prefiltration train with improved filtration capacity but rather to a prefiltration train suitable to improve the filtration capacity. Furthermore, claim 11 included amendments in

addition to the reformulation from a product to a use claim, in contrast to the claim in the cited decision. Decision T 22/09 concerned the reformulation of a method claim into a use claim and therefore also differed from the present situation.

The term "improvement" was unclear in the context of claim 11.

The term "IEX pool" was unclear for the same reasons as in claim 1. "IEX pool" was a product-by-process feature. Moreover, claim 11 was forward carrying, meaning that it did not define any steps prior to those in the claim. Therefore, in view of the claim wording this term could not correspond to an intermediate product. The "IEX pool" could not form part of the claimed use but instead corresponded to a starting composition, because the prefiltration train could not be used to prepare its own starting composition.

Auxiliary request 4 (filed as auxiliary request 4 with the statement of grounds of appeal)

Admittance into the appeal proceedings

The request should not be admitted into the appeal proceedings (Article 12(4)(6) RPBA) because it was filed too late.

It should have been filed during the opposition proceedings. The appellant was aware of the clarity issues relating to claim 15 as granted. At the oral proceedings the opposition division allowed time for filing amended claims.

The appellant cited decision T 315/21 in support of remitting the case to the opposition division, but in that decision the board considered a different situation, where the time available to the patent proprietor had been insufficient to file an appropriate amendment.

Admitting this request would go against procedural economy.

*Remittal of the case to the opposition division
(Article 11 EPC)*

It was settled case law that a party was not entitled to have a case decided at two instances.

Whether a case was to be remitted was to be decided on a case-by-case basis. In the present case, the decision was of interest to the public, as could be seen from the filing of eleven oppositions. None of the decisions cited in favour of remittal concerned such a situation, nor did any relate to a remittal for consideration of the requirements of Article 123(2) EPC.

A limited number of issues needed to be decided under Article 123(2) EPC. These had been discussed in detail in writing. The appellant would not be taken by surprise as the request to decide on Article 123 EPC before a remittal had already been filed with the replies to the appeal.

- XIII. The appellant requested
- that the decision under appeal be set aside and the case be remitted to the opposition division for further prosecution based on one of the sets of claims of

auxiliary requests 2 or 4 to 22, all filed with the statement setting out the grounds of appeal;

- that, "*in the event that the board considers the issue of whether or not the skilled person has read the description to be decisive for clarity of claim 1 of the MR, or of any claim in these proceedings (e.g. claim 1 of AR7 [...])*", a question on this point be referred to the Enlarged Board of Appeal (points 70, 145 and 148 of the statement setting out the grounds of appeal);
- further that, in the event the board considers that infringement scenarios are relevant for deciding on clarity of claim 1 of the main request, a referral on this point is made to the Enlarged Board of Appeal.

- XIV. Respondents II and III requested
- that the appeal be dismissed;
 - that auxiliary requests 3 to 7 and 9 to 19 not be admitted into the appeal proceedings;
 - that documents D90 and D91 not be admitted into the appeal proceedings; and
 - that the case be remitted to the opposition division after the board had decided the questions of clarity under Article 84 EPC and of Article 123(2) and (3) EPC.

Reasons for the Decision

Main request (filed as auxiliary request 2 with the statement of grounds of appeal) - Claims 1 and 11

Clarity (Article 84 EPC)

Claim 1

1. *Extent of the examination for compliance with the requirements of Article 84 EPC*
- 1.1 In the decision under appeal, the opposition division considered that the following expressions of claim 1 were not clear:
 - (i) "A method of improving the filtration capacity... during protein purification, consisting of"
 - (ii) "ion exchange chromatography pool" (in the following also "IEX pool")
- 1.2 Expression (i) was present in claim 1 as granted whereas expression (ii) was not. One point of dispute between the parties was whether the expression (i) could nevertheless be assessed for clarity in light of the Enlarged Board of Appeal's decision G 3/14. It was undisputed that expression (ii) was an amendment to the claim and therefore open to examination for clarity.
- 1.3 The respondents took the view that amendment (ii) introduced ambiguity into expression (i), as it was unclear whether the improvement in filtration capacity resulted exclusively from the steps following the wording "consisting of", or from steps implicit in the claim's preamble, such as those resulting in the "ion exchange chromatography pool". Consequently, they

considered that it was also unclear whether the method as claimed included steps in addition to those of cation exchange chromatography (CEX) and endotoxin removal (ER). The respondents considered that possible interpretations of claim 1 included

- that the expression "consisting of" applied to the claimed method, which consequently did not include steps other than CEX and ER;
- that "consisting of" applied only to the method of improving filtration capacity, which consisted of the steps CEX and ER, within a broader protein purification method; and finally,
- that the method of improving filtration capacity included the steps of CEX, ER and parvovirus filtration, within a broader protein purification method.

1.4 In decision G 3/14 (OJ 2015, A102), the Enlarged Board of Appeal addressed the question of whether, and to what extent, a patent as amended could be examined for compliance with the requirements of Article 84 EPC. It held that the patent as amended may be examined only to the extent that the amendment introduces non-compliance with Article 84 EPC (see Order). In its decision G 3/14 the Enlarged Board endorsed the approach that a lack of clarity arises out of an amendment when the lack of clarity did not exist before the amendment, meaning that it arises for the first time (see point 28 of the reasons). The Enlarged Board explicitly rejected an approach under which an amended patent could also be examined for clarity in cases where the amendment is considered to "highlight and focus attention" on a

previously existing ambiguity (see points 28 and 29 of the reasons).

1.5 Therefore in the present case, the issue to be decided with regard to the objections against expression (i), is whether expression (ii) introduces a lack of clarity. The board considers that in the present case, the objection to expression (i) arises from its wording alone and not from any amendments made to the granted claim. The alternative interpretations put forward by the respondents could be made independently of the amendments made after grant, i.e. "wherein the composition comprising the protein to be purified is an ion exchange chromatography pool". Indeed, the expression "A method of improving ... during protein purification" is already subject to the question of whether the claim is for a method of improving filtration capacity or a method of protein purification. The respondents also raised the question of which of these two methods, the steps following "consisting of" apply to. This question also arises from the wording of expression (i) alone.

1.6 In light of the above, the board concludes that the objections to expression (i) are due to wording already present in claim 1 as granted, which is not open to examination for the requirements of clarity in Article 84 EPC.

1.7 However, to examine compliance of the claimed invention with the EPC, the board must construe the claim.

2. *Interpretation of claim 1*

2.1 The wording "during protein filtration" in claim 1 means that the claimed subject-matter is a method, that

is itself part of an overall method of protein purification. In other words, the subject-matter of claim 1 is a method of protein purification. This method must include the steps of cation exchange chromatography, endotoxin removal and virus filtration.

2.2 The wording "consisting of" applies to "improving the filtration capacity", rather than to the overall method of protein purification, and does not limit the number of steps in the overall claimed method of protein purification.

2.3 The respondents argued that it is arbitrary and artificial to draw a distinction between an ion exchange chromatography (IEX) step for purifying the protein composition and the same IEX step that aims at improving the filtration capacity, because any steps that purify the protein composition will also improve the filtration capacity of the virus filter.

2.4 The board agrees with this view. Any method for protein purification that includes the steps defined in the claim (cation exchange and endotoxin removal, in addition to filtration through a parvovirus filter), will fall under the ambit of the claim regardless of their stated purpose, as long as they inherently achieve said purpose.

3. *Clarity of the expression "IEX pool"*

3.1 The opposition division held that the expression "IEX pool" defined a composition by means of the process of obtaining it (product-by-process definition). In the opposition division's view, the clarity of the expression "IEX pool" had to be assessed as if it were a product by process claim *per se*. In other words, it

had to be clear which identifiable and unambiguous technical features are imparted to the product by the process by which it is defined (see Case Law of the Boards of Appeal of the European Patent Office (CLBA), 2022, II.A.7.1). The respondents argued that methods are defined by the entities which are processed and the activities of processing them, and that the feature "IEX pool" defined one such entity.

- 3.2 As is established case law, the claims are to be read by the skilled person giving the terms their ordinary meaning, in the context of their technical field and taking into account the claim category (see T 681/01, point 2.1.1. of the reasons and other decisions cited in CLBA, II.A.6.3.4).
- 3.3 The technical context of claim 1 is protein purification. The claim is a process claim, defined by process steps. Taking this into account, the question to be addressed is how the skilled person would have understood this feature. The board considers that the skilled person would read "IEX pool" in claim 1 as referring to a composition which results from an IEX step. The alternative reading put forward by the respondents is that the composition may be the result of other processing steps as long as it is identical to one obtainable by IEX, since it is defined in terms of product-by-process. However, in the context of the claim, this is not a reasonable reading of this term given that the claim specifically mentions IEX. Thus, the skilled person would understand that the "IEX pool" must come from an IEX step, because the feature serves to define the stage of protein purification at which the two steps of endotoxin removal and CEX occur in the claimed method.

- 3.4 The respondents interpreted the IEX feature as product defined by the process for its production and therefore considered that the clarity requirements for such a claim applied, i.e. the definition of the product, by means of a process, had to be clear.
- 3.5 However, claim 1 is not directed to a product but to a process. Moreover, feature (ii) defines an intermediate in the process of purification and not a starting composition in a method of manufacturing a product. For this reason, the question of what the exact characteristics of the IEX pool are is not relevant.
- 3.6 No different conclusion is reached in light of the case law cited by the parties, as follows:
- 3.6.1 In decision T 219/83 the board considered a claim defining a product in terms of its process of production. The board held that such a claim must be interpreted as directed to the product *per se*, independently of the process, and its patentability must be assessed based on the product independently of the process for its preparation (see point 10 of the reasons). This decision is not relevant for present claim 1, which is not directed to a product.
- 3.6.2 In decision T 81/14 the board considered a claim defining a use and including a product-by-process feature. The board held that the requirements developed for product-by-process claims are in general to be applied also in the case of a claim directed to the use of such a product. The claim in question was drafted as follows: "Use of a sintered cement carbide body obtained according to the method of any one of claims 1 to 7 for the production of a cutting tool". Since the board had not been persuaded that it would not have

been possible to define the product by structural features, the definition lacked clarity (see reasons 3.4., 3.7., 3.8). Unlike claim 1 in present case, the claim defined the use of a starting product for the manufacture of a final product. In the present case a clear definition of the claimed method by means of method steps is not precluded by an unclear definition of a starting product. Rather, the claim defines that the CEX and ER steps are applied after IEX. In such a case the specific characteristics of the IEX pool are not relevant for a clear definition of the method of protein purification. This decision is not relevant for present claim 1, which is not directed to a method of manufacture defined by its starting material but rather to a method defined by a sequence of method steps.

3.6.3 In decision T 2053/13 the board also considered a claim defining a use and including a product-by-process definition. The claim defined a use which involved mixing three components, one of which was defined in terms of a product-by-process. The board held that the steps of preparing this component were not part of the claimed method (point 1.5.5 of the reasons) and thus the component was defined in terms of a product-by-process. The board held that the principle applied in decision T 81/14 applied in the claim before it too. However, present claim 1 is directed to a method of protein purification. The claim considered in the cited decision was directed to a method of manufacturing a product by the mixing of three components, so that a clear definition of each component was required.

3.6.4 In conclusion, none of the cited decisions concerns a claim defining a method as claim 1, which does not define a method where the starting product is decisive

for the final product being manufacture, but rather defines steps of processing.

3.6.5 Decision T 1471/16 on the other hand is an example where the board assessed a claim for a product, where the definition implied process steps. The board concluded nevertheless that the claim was clear. Specifically, the board considered that some of the features defining the claimed product related to its method of production, such as "cell fluid as harvested" and "the fluid as separated from cell, cell debris and aggregates". The board considered that in the circumstances of the case the expressions limited the claim from products prepared by other method steps (see point 8 of the reasons). It was decisive that the claimed product, a "harvested cell culture fluid", was seen as an intermediate in the further purification of the protein contained in said fluid (see point 10 of the reasons).

4. *Clarity of the expression "therapeutic antibody or fragment thereof"*

4.1 The respondents also objected to the expression "therapeutic antibody" as unclear. Specifically, it was unclear whether the term "therapeutic" imparted any limitations, and if so, what they were. Moreover, if "therapeutic" were considered to limit the antibody, then the scope of the claim would change over time depending on when an antibody was recognised as having therapeutic use. Furthermore it was asked if "therapeutic" limited the antibody in claim 1 in terms of the antibody purity or by its approval by regulatory authorities.

4.2 The board is not persuaded by the respondents' arguments. In the context of the claimed invention, i.e. a method of protein purification, the skilled person would understand that "therapeutic antibody" refers to any antibody of potential interest for therapy, and that "therapeutic" plays no significant role in the claimed method. Thus "therapeutic" covers a broad range of antibodies. However, it is established in the case law of the boards of appeal that a broad claim is not necessarily unclear (see T 688/91, point 3.4 of the reasons, and decisions cited in CLBA, 10th ed. 2022, II.A.3.3). The respondents cited decision T 1702/15 as dealing with an analogous situation. However, in contrast to the claim considered in that decision, claim 1 before the board is not directed to a product. In conclusion, the expression "therapeutic antibody" is not unclear in the context of claim 1. The same reasoning applies to the expression "fragments thereof".

5. *Conclusion on clarity of claim 1*

5.1 In light of the foregoing the board concludes that the amendments to claim 1 does not introduce a lack of clarity under Article 84 EPC.

Claim 11

6. Claim 11 is drafted in the form of a non-medical use claim and relates to the non-medical use of a "prefiltration train" (an apparatus), consisting of a cation exchange membrane adsorber and an endotoxin removal membrane adsorber, for "improving the filtration capacity of a parvovirus filter during protein purification".

7. Claim 11 differs from claim 1, which latter relates to a purification process comprising carrying out certain steps, in that it defines a use both by the purpose or effect of "improving the filtration capacity of a filter during protein purification" and by steps carried out. In contrast to the situation in claim 1, the prefiltration train must achieve the purpose stated in the claim. This is consistent with the claim wording because the two steps "processing an IEX pool over the prefiltration train" and "filtering the subsequent pool with said parvovirus filter" are both responsible for achieving the effect defined in the claim. Therefore, the claim is read as put forward by the respondents, namely its subject-matter is a method of processing a protein composition which is an "IEX pool". In conclusion, while in claim 1 the feature "IEX pool" serves to define the stage of protein purification at which the two steps of endotoxin removal and CEX occur in the claimed method, in claim 11 it defines the starting composition that will be processed over the prefiltration train.
8. In considering the clarity of claim 11 it is noted that since the claim does not relate to a longer overall method, the term "IEX pool" as used in this claim defines a composition that is directly applied to the prefiltration train. In such circumstances, the considerations that led the board to hold that claim 1 was not unclear with respect to the term "IEX pool" do not hold for claim 11. Instead, in claim 11 the skilled person can only understand what the claimed use is if they also know what the IEX pool is.
9. In the context of claim 11 this is not the case because the characteristics imparted to a protein composition by IEX depend on a number factors, such as whether the

chromatography is CEX or AEX (which will affect which impurities are removed; see the patent, paragraph [0134]) and the effect of pH on impurity removal by IEX. It follows that claim 11 is not clear.

Conclusion on clarity of the main request

10. It follows that the main request lacks clarity.

Auxiliary request 4 (filed as auxiliary request 4 with the statement of grounds of appeal)

Admittance into the appeal proceedings (Article 12(4) and (6) RPBA

11. This request was filed for the first time with the statement of grounds of appeal. It differs from the main request, which is identical to auxiliary request 2 considered by the opposition division, only in that claims 11 and 12 were deleted.

12. The respondents requested that it be not admitted into the appeal proceedings, on the grounds that it could and should have been filed during opposition proceedings and that its filing was contrary to procedural economy.

13. Under Article 12(4) RPBA, auxiliary request 4 constitutes an amendment to the appellant's case, and as such it may be admitted at the discretion of the board. Furthermore, under Article 12(6) RPBA, the board shall not admit requests which should have been submitted during the proceedings leading to the decision under appeal, unless the circumstances of the appeal justify their admittance.

14. Therefore, a question to be addressed is whether the appellant should have filed this request during the opposition proceedings.

15. The board agrees with the respondents that objections against claim 15 as granted were known to the appellant during opposition proceedings. However, the appellant argued that at oral proceedings the opposition division announced that both claims 1 and 13 of the main request were not clear. This was not contested by the respondents. It is also consistent with the minutes of the oral proceedings before the opposition division (see point 3.6.1.). The board considers that in view of the conclusion of the opposition division, during oral proceedings, that both claims 1 and 13 of the main request did not comply with the requirements of Article 84 EPC, there was no reason for the appellant to file an amended claim request where claim 1 was maintained and only claim 13 was deleted, i.e. the present claim request, at that stage. The board has not been presented with reasons why the appellant should have filed a request where the amendments differed between claims 1 and 13. The board considers that, in the present case, where eleven oppositions to the patent had been filed, the appellant's argument that in opposition proceedings they had addressed the main objections of the multiple opponents submitting fallback positions, is valid. In this way the appellant complied with their duty to present their case as early and completely as possible.

16. In view of the above considerations, the board decided to admit the request into the appeal proceedings.

Clarity (Article 84 EPC)

17. Both respondents II and III have made objections of lack of clarity against claim 1 of this claim request (which is identical to claim 1 of the main request). For the reasons set out above for the main request, the board concluded that the amendments to claim 1 did not introduce a lack of clarity under Article 84 EPC (see points 1. to 5.1).

*Remittal of the case to the opposition division
(Article 11 RPBA)*

18. The parties had opposing requests in this regard. The appellant requested remittal for consideration of any issue other than clarity, whereas the respondents requested that the board decide on compliance with the requirements of Article 123(2) and (3) EPC before remitting the case.
19. The decision under appeal only dealt with the question of clarity under Article 84 EPC.
- 19.1 This circumstance on its own amounts to special reasons in the sense of Article 11 RPBA. A particular aspect which in this context, lead the board to decide to remit the case was that, despite the decision on clarity and interpretation of the claims, the respondents have made objections under Article 123(2) EPC that are not straightforward to deal with. In view of the primary object of appeal proceedings being to review the decision under appeal in a judicial manner (Article 12(2) RPBA), the board dealt only with the requirements of Article 84 EPC and decided to remit the case to the opposition division for consideration of the other requirements of the EPC.

20. The board considers that in the present case the number of parties interested in a final decision does not outweigh the above considerations.

Requests to refer questions to the Enlarged Board of Appeal

21. The appellant had two conditional requests to refer questions to the Enlarged Board of Appeal.
- 21.1 A first request related to the use of the description for assessing clarity of a claim. Four questions were formulated (see statement of grounds of appeal, point 148). The request was however on condition that, *"the board considers the issue of whether or not the skilled person has read the description to be decisive for clarity of claim 1 of the MR, or of any claim in these proceedings (e.g. claim 1 of AR7 [...])"* (see point 70 of the statement of grounds of appeal) or, in an alternative formulation, on condition that the board *"is of the opinion that the claims are unclear when considered in isolation such that this point is decisive for the board's final decision"* (see point 148 of the statement of grounds of appeal).
- 21.2 The conditions set by the appellant for referring these questions were not fulfilled. Only claim 11 was considered to lack clarity. However, for this finding the reliance on the description did not play a role. In other words, when taking into account the description the board still comes to the conclusion that the expression "ion exchange chromatography pool" is unclear in the context of claim 11. Whether according to the description a step of ion exchange chromatography is carried out before or after the other steps in the claim does not play a role, because what

is decisive is that the use claimed does not leave room for additional steps.

22. A second request related to an argument put forward by the respondents which used infringement scenarios to explain the alleged lack of clarity. This request was conditional on the board considering "*that infringement scenarios are relevant for deciding on clarity of claim 1*".

22.1 This condition for referring the question was not fulfilled, as infringement scenarios played no role and the board concluded that claim 1 was clear. Indeed, the requirement that the claimed subject-matter must be defined so that the public, i.e. an infringer, is left in no doubt about what the subject-matter for which protection is sought actually is (cf. G 2/88, OJ EPO 1990, 93, reasons 2.5) has no impact on the principle that the test for compliance with the clarity requirement of Article 84 EPC is carried out from the standpoint of the skilled person.

Request to decide on the admittance of auxiliary requests 5 to 7 and 9 to 19 and documents D90 and D91 and request to decide in substance on auxiliary requests 20 to 22

23. Respondents II and III requested that the board decide on these issues. However, documents D90 and D91, filed by the appellant, were not relevant for the present decision. For this reason, the board sees no need to decide on their admittance. There was also no need to decide on admittance of lower ranking requests, on which no decision in substance was taken.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the opposition division for further prosecution.

The Registrar:

The Chairman:



A. Wille

A. Chakravarty

Decision electronically authenticated