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Datasheet for the decision of 29 March 2023

Case Number: T 0900/21 - 3.3.05

Application Number: 17157670.5

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Title of invention:
OVERLOAD AND ELUTE CHROMATOGRAPHY

Patent Proprietor:
F. Hoffmann-La Roche AG

Opponent:
Hoffman Eitle Patent- und Rechtsanwälte Partnerschaftsgesellschaft mbB

Headword:
Overload and elute chromatography/Hoffmann La Roche

Relevant legal provisions:
EPC Art. 100(b), 56, 83, 84
RPBA 2020 Art. 13(2)

Keyword:
Sufficiency of disclosure - main request and auxiliary requests 1-4, 6, 8, 9, 13, 13a - (no)
Inventive step - auxiliary requests 5, 7, 10-12 - (no)
auxiliary request 14 allowable

Decisions cited:
G 0003/14, T 0409/91, T 0435/91, T 0939/92, T 0172/99, T 0458/07, T 0608/07, T 0593/09, T 2114/16, T 2759/17, T 0995/18, T 2843/19

Catchword:

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Case Number: T 0900/21 - 3.3.05

D E C I S I O N
of Technical Board of Appeal 3.3.05
of 29 March 2023

Appellant: (Opponent)	Hoffman Eitle Patent- und Rechtsanwälte Partnerschaftsgesellschaft mbB Arabellastr. 30 81925 München (DE)
Representative:	Hoffmann Eitle Patent- und Rechtsanwälte PartmbB Arabellastraße 30 81925 München (DE)
Respondent: (Patent Proprietor)	F. Hoffmann-La Roche AG Grenzacherstrasse 124 4070 Basel (CH)
Representative:	Mewburn Ellis LLP Aurora Building Counterslip Bristol BS1 6BX (GB)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 23 April 2021 rejecting the opposition filed against European patent No. 3257564 pursuant to Article 101(2) EPC.**

Composition of the Board:

Chairwoman	S. Besselmann
Members:	G. Glod
	O. Loizou

Summary of Facts and Submissions

I. The appellant's (opponent's) appeal lies from the opposition division's decision rejecting the opposition against European patent EP-B-3 257 564.

II. The following documents cited in the impugned decision are of relevance here:

D7: Ion Exchange Chromatography and Chromatofocusing, Handbook from GE Healthcare, chapter 2, pages 26 to 58
D10: Harinarayan C. et al., Biotechnology and Bioengineering, 2006, Vol. 95(5), pages 775 to 787
D35: Colour copy of Figure 1 of the patent in suit
D38: Multimodal Chromatography, Handbook from GE Healthcare, 2013, chapter 2, pages 17 to 20, 25, 30
D39: Experimental data of the patent proprietor relating to hydrophobic interaction chromatography
D41: US 2007 0060741 A1

III. Claim 1 of the patent as granted (main request) reads as follows:

"*1. A method for purifying an antibody from a composition comprising the antibody and one or more contaminants, said method comprising*
a) loading the composition onto a mixed mode, an ion exchange, a hydrophobic interaction, or an affinity chromatography material in an amount in excess of the dynamic binding capacity of the chromatography material for the antibody using a loading buffer, wherein the partition coefficient of the chromatography material for the antibody is greater than 30,

b) eluting the antibody from the chromatography material under conditions wherein the one or more contaminants remain bound to the chromatography material using an elution buffer, wherein the elution buffer has a conductivity less than the conductivity of the loading buffer, and
c) pooling fractions comprising the antibody in the chromatography effluent from steps a) and b)."

Compared with the main request, claim 1 of auxiliary request 1 includes the underlined amendment at the end of the claim.

"*1. [...] c) pooling fractions comprising the antibody in the chromatography effluent from steps a) and b); wherein the chromatography material is a chromatography column.*"

Compared with the main request, claim 1 of auxiliary request 2 includes the underlined feature.

"*1. A method for purifying an antibody from a composition comprising the antibody and one or more contaminants, wherein the composition is an eluent from an affinity chromatography, said method comprising [...].*"

Compared with the main request, claim 1 of auxiliary request 3 includes the underlined feature.

"*1. A method for purifying an antibody from a composition comprising the antibody and one or more contaminants, wherein the composition is an eluent from protein A chromatography, said method comprising [...].*"

Compared with the main request, claim 1 of auxiliary request 4 includes the following amendments (underlined and struck through).

"*1. [...] a) loading the composition onto a mixed mode, an ion exchange, or a hydrophobic interaction~~, or an affinity~~ chromatography material in an amount in excess of the dynamic binding capacity [...].*"

Compared with the main request, claim 1 of auxiliary request 5 includes the following amendments (underlined and struck through).

"*1. [...] a) loading the composition onto a mixed mode, ~~an ion exchange,~~ or a hydrophobic interaction~~, or an affinity~~ chromatography material in an amount in excess of the dynamic binding capacity [...].*"

Compared with the main request, claim 1 of auxiliary request 6 includes the following amendments (underlined and struck through).

"*1. [...] a) loading the composition onto a mixed mode, or an ion exchange~~, a hydrophobic interaction, or an affinity~~ chromatography material in an amount in excess of the dynamic binding capacity [...].*"

Compared with the main request, claim 1 of auxiliary request 7 includes the following amendments (struck through).

"*1. [...] a) loading the composition onto a mixed mode~~, an ion exchange, a hydrophobic interaction, or an affinity~~ chromatography material in an amount in excess of the dynamic binding capacity [...].*"

Compared with the main request, claim 1 of auxiliary request 8 includes the following amendments (underlined).

"*1. [...] wherein the partition coefficient of the chromatography material for the antibody is greater than 30, and wherein the loading density is greater than about 200 g/L [...].*"

Claim 1 of auxiliary request 9 combines the amendments of auxiliary requests 1 and 4.

Claim 1 of auxiliary request 10 combines the amendments of auxiliary requests 1 and 5.

Claim 1 of auxiliary request 11 combines the amendments of auxiliary requests 1 and 7.

Claim 1 of auxiliary request 12 combines the amendments of auxiliary requests 1, 3 and 7.

Compared with the main request, claim 1 of auxiliary request 13 includes the following amendments (underlined and struck through).

"*1. [...] wherein the partition coefficient of the chromatography material for the antibody is greater than ~~30~~ 100,[...].*"

Claim 1 of auxiliary request 13a combines the amendments of auxiliary requests 6 and 13.

Claim 1 of auxiliary request 14 combines the amendments of auxiliary requests 7 and 13.

IV. Oral proceedings took place on 29 March 2023.

V. The appellant's arguments as far as relevant to the present decision are reflected in the reasoning below and can be summarised as follows for auxiliary request 14.

The requirements of Articles 56, 83 and 84 EPC were not met. The skilled person would consider the teaching of D41, in particular Run 8 of Table 6.2.1, and arrive at the claimed subject-matter for the same reasons as for the higher-ranking requests. This objection should be considered because it was raised in reply to the board's preliminary opinion. In addition the expression Kp>100 was so ill-defined that it led to problems with sufficiency and clarity. The skilled person would not know how to determine Kp.

VI. The respondent's arguments as far as relevant to the present decision can be summarised as follows.

The invention was sufficiently disclosed. Example 1 of the patent showed how an operating window for overload and elute chromatography could be determined. This was applicable to all types of chromatography covered by claim 1. D10 confirmed that it was possible in ion-exchange chromatography to elute a protein with decreasing conductivity. There was no evidence that showed the contrary. D38 (figure 2.4) showed that a mixed-mode material had the characteristics of both an ion exchange material and a hydrophobic interaction material. Therefore, it could be concluded that the method which worked for mixed-mode materials could also work for some ion-exchange materials.

Regarding inventive step, runs 10 to 12 of Table 5.2.1 of D41 could not be taken as the closest prior art,

since they related to comparative examples that were performing worse than the experiments according to the teaching of said document 41. In accordance with T 2114/16 and T 2759/17, a disadvantageous starting point should not be selected. Even if the skilled person started from the above-mentioned runs, that skilled person would modify them to provide a method including a Kp<20 and having an isocratic wash. The objective technical problem was to provide an improved method. The problem had to be considered solved, since it followed from the trend shown in Figure 5 of the patent in suit that a decrease in conductivity of the elution buffer was associated with lower pool volume compared with an isocratic wash. The solution to this problem was not obvious, since the skilled person had no motivation to change the isocratic wash to an elution buffer having a lower conductivity than the loading buffer. Even if the problem were merely to provide an alternative, the skilled person would not make two separate buffers where one would suffice. In addition there would be a risk of eluting the impurities.

The appellant's arguments based on Table 6.2.1 of D41 had been submitted for the first time during oral proceedings and should not be taken into account, in accordance with Article 13(2) RPBA 2020.

VII. The appellant (opponent) requested that the decision under appeal be set aside and that the patent be revoked in its entirety.

The respondent (patent proprietor) requested that the appeal be dismissed (main request) or , alternatively, that the patent be maintained in amended form on the basis of one of auxiliary requests 1 to 16, all requests submitted with the reply to the appeal, or

auxiliary request 13a filed with the respondent's letter dated 18 January 2023.

Reasons for the Decision

Main request

1. Article 100(b) EPC

The established case law of the boards of appeal considers that the requirements of sufficiency of disclosure are met if the invention as defined in the independent claims can be carried out by a person skilled in the art, using their common general knowledge, over the whole scope of the claim without undue burden (e.g. T 409/91, Reasons 3.5; T 435/91, Reasons 2.2 and 2.2.1).

In the present case, claim 1 relates to a method for purifying an antibody from a composition comprising the antibody and one or more contaminants, wherein the composition is (over)loaded onto one of four different types of possible chromatography materials, the antibody is eluted and the antibody-containing fractions are pooled.

One of the possible materials is an ion-exchange chromatographic material. According to prevailing technical opinion relating to the elution of components from an ion-exchange material, the interaction is lowered and thus elution is obtained if the conductivity of the buffer is *in*creased. This is confirmed by D7 (Figure 19 on page 38; page 32, mentioning a *maximum* ionic strength for binding and a *minimum* ionic strength for elution) and by D10 (abstract). The latter discloses a domain where the

dynamic binding capacity increases with increasing conductivity and decreasing protein charge, but describes this as unexpected, meaning that the existence of this domain was contrary to expectations and established practice.

Claim 1 specifies elution using an elution buffer having a conductivity *less* than that of the loading buffer, and thus specifies conditions of the elution step which would typically be associated with an *increased* interaction with the ion-exchange chromatographic material, i.e. *increased* binding.

According to established case law, in the case of an invention which goes against the prevailing technical opinion, it is the patent proprietor that needs to prove sufficient disclosure (Case Law of the Boards of Appeal of the EPO, 10th edition, 2022, III.G.5.1.2.c)).

The respondent argued that there was no prevailing technical opinion for the claimed method, i.e. overload and elute chromatography, since it constituted a completely new way of purifying an antibody. In such a case, however, it is even more important for the skilled person reading the patent to be able to find guidance allowing them to practise the invention over the whole scope claimed.

Furthermore, step b) generally relates to the elution of the antibody from an ion-exchange material where it is strongly bound (Kp>30). In that respect, this step does not actually differ from classic chromatography, which includes the removal of components bound to the column, for example the elution step in bind-and-elute chromatography.

Example 11 of the patent in suit (paragraph [0324]) states that overload and elution chromatography could be applied to different types of resins. However, the only example given with an ion-exchange column (Poros XS) is not in line with claim 1. Indeed, elution was performed with a *higher* conductivity, as the skilled person would have expected.

The respondent relied on D10 to show that an increase of capacity with increasing conductivity was possible. However, D10 does not represent common general knowledge. It confirms that the results shown therein were unexpected, as indicated above. Furthermore Table III of D10 (page 782) confirms that the equilibrium binding capacity (Q_{eq} (g/L)) increases with decreasing conductivity, as expected by the skilled person. Therefore, D10 is of no help to the respondent's case.

Example 1 of the patent shows, for a mixed-mode resin, how the optimal conditions ("sweet spot") for overload and elute chromatography can be determined for an antibody/mixed-mode resin pair (see Figures 1a to 1c; see also D35). Based thereon, loading and elution conditions were optimised for mixed-mode chromatography (Examples 2 to 4). In these mixed-mode examples, elution was obtained with a *lower* conductivity. However, this does not allow any conclusion to be drawn regarding traditional ion-exchange materials where ion exchange is the only interaction type. D38 relates to multimodal (mixed-mode) media and discloses in Figure 2.4 that these media include a combination of interaction modes. The strength of the individual interactions depends on the overall process conditions. Further according to Figure 2.4, at low conductivity, binding to the ion-exchange part would be expected; at high conductivity, hydrophobic interaction would be

expected. This would mean that elution from the ion-exchange part was to be expected at high conductivity, which is in line with the skilled person's expectation for traditional ion-exchange chromatography, as also depicted in the figure.

Example 1 of the patent in suit, taken together with D38, thus does not lead to the expectation that a similar "sweet spot" - where elution would be possible using an elution buffer having a conductivity *less* than the conductivity of the loading buffer - could be identified for ion-exchange chromatography materials.

Although some ion-exchange columns are indicated in paragraphs [0079] and [0080] of the patent in suit, there is not a single example using one of these columns with a *lower* conductivity for elution.

It may be possible to elute some of the antibody from an (overloaded) ion-exchange chromatographic material at a conductivity which is only slightly lower than that of the loading buffer, close to an isocratic wash. However, this only concerns embodiments near the border of the claim and cannot be generalised for the whole area claimed.

As admitted by the respondent, it is probably not possible to find an operating window for overload and elute chromatography for each and every chromatography material. Therefore, the skilled person trying to implement claim 1 with respect to ion-exchange chromatography would have to identify not only a suitable antibody/ion-exchange material pair but also the working conditions for each pair as well as identifying where overload and elute chromatography is possible contrary to their expectations and the

established practice, and they would have to do all this without any guidance from the patent. This amounts to an undue burden and cannot be considered to be in line with the requirements of sufficiency of disclosure as established in Article 83 EPC and the case law.

This case differs from the situation underlying T 458/07, in which the claimed ion exchange chromatography method built on the "standard" way of conducting ion exchange chromatography (Reasons 22), and where it was found that the skilled person knew that fine-tuning of the chromatography process could be achieved on the basis of the well-known physico-chemical principles on which ion-exchange chromatography relied (Reasons 21, in particular the last paragraph). One such principle is that proteins bind to the resin if the conductivity is low (Reasons 21). T 458/07 thus did not concern a method where the interactions of the antibody with the ion-exchange material - and hence the elution behaviour - were contrary to the prevailing technical opinion.

The board concludes that the requirements of Article 83 EPC are not met insofar as the claim relates to ion-exchange chromatography.

Therefore, the main request must fail.

Auxiliary requests 1 to 4, 6, 8, 9, 13 and 13a

2. Article 83 EPC

It was not disputed by the respondent that these requests also included ion-exchange chromatography and that the considerations in this regard were the same as for the main request. The board's conclusion with

respect to the main request thus equally applies to auxiliary requests 1 to 4, 6, 8, 9, 13 and 13a.

Therefore, auxiliary requests 1 to 4, 6, 8, 9, 13 and 13a are not allowable either.

Auxiliary request 5

3. Article 56 EPC

3.1 The present invention relates to a method for purifying an antibody from a composition comprising the antibody and one or more contaminants.

3.2 Document D41 relates to the same general purpose of recovering a purified product, for instance an antibody, from a load fluid including one or more impurities (claim 1 and paragraphs [0087]-[0089]). Run 11 of Table 5.2.1 of D41 is a suitable starting point for the evaluation of inventive step of the method in claim 1 at issue. This run relates to ceramic hydroxyapatite chromatography, which is considered a mixed-mode chromatography. It used a starting composition which was a partially purified antibody pool originating from a Protein A step. The column was overloaded, there was an isocratic wash, and the product was recovered in the column effluent during the load cycle and in some column volumes of the wash fraction (paragraphs [0215] to [0225]), i.e. pooled. The operating mode in Run 11 was strong-binding, with a partition coefficient (Kp) of 32.7. Although this run is not the highest performing one, it still qualifies as a possible starting point, in particular since the skilled person realises that the product recovery (86%) is similar to that of runs 1 to 10, and very close to the optimal range given in Figure 11. It not only

fulfils the general purpose of D41, but it also fulfils the functional requirements of the claim at issue, namely for an antibody to be purified and for one or more contaminants to remain bound. It is thereby borne in mind that the claim neither specifies nor implies any degree of purification, or the extent to which one or more contaminants remains bound, or the yield.

The use of Run 11 as a starting point is completely in line with the decisions cited by the respondent. In particular, in T 2114/16 (Reasons 5.3.4), a comparative example from the prior art was not considered as a suitable starting point since it had the lowest internal bond strength and the technical problem was to increase the mechanical strength of paper. In the case at hand, the situation is different since the aim is to purify an antibody, which is also the case in D41. Run 11 is not a comparative example, but is in line with claim 1 of D41 and it provides a degree of purification almost as good as the optimal range. In addition, it has most features in common with claim 1.
This choice of the closest prior art is also in agreement with T 2759/17 (Reasons 5.5), which indicates that the skilled person would look for a prior-art disclosure that is in the same technical field and aims at the same or a similar purpose or effect. This is definitely the case for Run 11 of D41, since the aim is also to purify an antibody, and product recovery of 86% is reached.

3.3 The alleged problem to be solved is to provide an improved method for purifying an antibody.

3.4 It is proposed to solve the problem by a method according to claim 1 characterised in that the elution

buffer has a conductivity less than that of the loading buffer.

3.5 It is necessary to evaluate whether said problem is solved successfully over the whole range claimed. The respondent relies on Examples 4 and 10 and on Figure 5 of the patent as evidence for the successful solving of the alleged problem. However, the board is not convinced that the effect is present over the whole range claimed.

The respondent argued that the difference in conductivity was associated with a lower pool volume, which would be highly beneficial on an industrial scale. However, the issue of whether an improved method is obtained cannot be assessed on the basis of the pool volume alone, because the matter is interlinked with the antibody yield and the contaminant removal (paragraph [0089]; Examples 2 and 4). Moreover, no direct comparison with the closest prior art is available, and the data presentation in the patent does not allow the conclusion to be drawn that the respondent's argument applies over the whole range claimed.

Example 4 concerns elution optimisation for a very specific case at a defined pH and explicitly mentions that higher conductivity buffers (all having a conductivity less than the loading buffer) resulted in tailing and were not really considered sufficient to obtain the desired results (paragraph [0313] and Figure 5 of the patent). Although these elution buffers were not considered optimal, they still exhibited a difference in conductivity of at least 1.5 mS/cm compared to the loading buffer.

Example 10 is of no help in that respect, since the difference between load conditions and elution conditions was 4.5 mS/cm. Furthermore the Kp in OEC is > 14 000 and there is no evidence that the same results would be obtained with a Kp close to 30. The comparison in Example 10 between WPC and OEC contains more distinguishing features than D41 and claim 1 at issue.

Step b) of claim 1 does not include any indications concerning how much of the antibody should be eluted, how many column volumes of elution buffer are to be applied, what qualifies as "wherein the one or more contaminants remain bound to the chromatography material" and, importantly, it gives no indication of what conductivity difference the expression "a conductivity less than the conductivity of the loading buffer" implies. Step b) thus encompasses the entire range of conditions falling within (but excluding) the extremes represented by a stripping step (elution of all the antibody and all the contaminants) on the one hand and an isocratic wash on the other hand. It may be true that the problem could possibly be considered solved if the elution was carried out under optimised elution conditions - wherein the Kp of the antibody was clearly different from the Kp of the contaminant - such as the conditions described for the specific case of Example 10 (paragraph [0322]). Such conditions are, however, not part of step b) of claim 1.

Notwithstanding the question of whether the opposition division exercised its discretion in a correct manner when not admitting D39, the latter does not seem to be of any help. Indeed, in the comparative example, the elution conditions were not isocratic, but the elution buffer had higher conductivity (50.2 mS/cm) than the load (47.5 mS/cm).

3.6 Consequently the problem needs to be redefined in less ambitious terms and can be seen as the provision of an alternative method for purifying an antibody.

3.7 The solution to this not-very-ambitious problem is obvious, since D41 explicitly discloses that slight variations between the load end effluent are included in the teaching of D41 (paragraph [0053]). The skilled person would not expect there to be a greater risk of eluting the impurities because the contaminant binding is less affected by the operating conditions in the relevant range (Figure 11 and paragraph [0225] of D41), in particular if the variation is small. In addition, paragraph [0072] discloses that isocratic wash conditions are not as effective with high Kp values. The respondent's argument that the skilled person would not change the isocratic buffer, since that would complicate the process, is not convincing either, because D41 considers the load conditions and the wash conditions separately (Table A; paragraphs [0219] and [0221]). Therefore, the skilled person would contemplate adjusting them separately. Although there are many possible variations of the operating conditions, which include salt concentrations (see paragraph [0012]), the changing of the elution buffer such that it has a conductivity less than that of the loading buffer is certainly one of the possibilities. A mere arbitrary choice made from among the possible solutions cannot involve an inventive step (T 939/92, Reasons 2.5.3).

3.8 Consequently the subject-matter of claim 1 of auxiliary request 5 does not involve an inventive step. This request is not allowable either.

Auxiliary requests 7 and 10 to 12

4. Article 56 EPC

During oral proceedings the respondent acknowledged that the amendments made in auxiliary requests 7 and 10 to 12 did not change the considerations regarding inventive step of auxiliary request 5. These auxiliary requests include the alternative relating to mixed-mode chromatography. The additional features (the chromatography material being a chromatography column; the composition being an eluent from protein A chromatography) do not provide any additional delimitation from D41. Thus, the same conclusion applies.

Auxiliary requests 7 and 10 to 12 are not allowable either, for lack of inventive step.

Auxiliary request 14

5. Article 83 EPC

The requirements of Article 83 EPC are met for the following reasons.

5.1 Sufficiency is established on the basis of the patent as a whole and not only on the basis of the claims. The skilled person understands from the patent that purifying only requires that the composition containing the antibody should have a smaller amount of contaminants after the method has been executed than before (see also paragraph [0024]). To achieve the purification, a composition comprising the antibody should be loaded onto a mixed-mode chromatography material in amount that exceeds the dynamic binding

capacity. The dynamic binding capacity is known to the skilled person and is also defined in paragraph [0061] of the patent. The chromatography material should have a partition coefficient (Kp) for the antibody of greater than 100. The skilled person trying to put the method into practice learns from paragraph [0062] what partition coefficient means in the current case. Paragraph [0303] explains how the partition coefficient is determined

The elution step b) only requires that the conductivity of the elution buffer should be less than that of the loading buffer. The skilled person definitely knows how to adjust conductivity.

Step c) relates to pooling of the fractions and is indisputably known to the skilled person.

5.2 The appellant mainly argued that the partition coefficient was an unusual parameter that could not be determined with the required accuracy. The appellant thereby relied on numerous theoretical and partially speculative calculations, but has omitted to submit evidence reproducing the teaching of the patent. It may be true that there are different ways of calculating the partition coefficient, but there is no evidence that large variations would be obtained when reproducing the teaching given in paragraph [0303]. Furthermore variations in the determination of the partition coefficient are of no relevance to the question of sufficiency in the case at hand, where the partition coefficient is only limited by a lower end point. Values of Kp far greater than 100 are possible, for instance a Kp of 14 000 in Example 10 of the patent in suit (log Kp=4.15 in Table 15). Even if it were accepted that the partition coefficient is an

ambiguous, unusual parameter in the current case, the alleged variation does not permeate the whole claim such that a problem of sufficiency could possibly arise (see T 608/07, Reasons 2.5.2). The current case differs from T 593/09 and T 172/99, in which the ambiguous parameter was limited to a small range.

5.3 Claim 1 is now limited to mixed-mode chromatography. The patent provides several examples concerning how to practise the claimed method and, in particular, Example 1 relates to mixed-mode chromatography for the determination of the operating window. There is also no step that goes against the prevailing technical opinion. Therefore, and in view of the lack of any evidence contradicting the examples of the patent, it is concluded that the skilled person will find enough guidance to work the method according to claim 1 of auxiliary request 14.

6. Article 84 EPC

The appellant argued that the amendment (Kp > 100) did provide a basis for objection under Article 84 EPC, since it was not clear how Kp > 100 should be determined.

However, any potential clarity problem is linked to the partition coefficient and not to the value itself. The partition coefficient was already part of claim 1 as granted. The only amendment is the value and therefore the objection may not be examined, in view of G 3/14 (published in OJ 2015, 102; Order).

7. Article 13(2) RPBA 2020

The appellant mainly based its inventive-step objection on Run 8 of Table 6.2.1 of D41.

This objection was raised for the first time during oral proceedings before the board and constitutes an amendment of the appellant's appeal case. The objection is not simply a complementation of the already existing case. Indeed, the appellant relied on new facts, namely the data of Table 6.2.1 of D41, to argue inventive step against the request here. Article 13(2) RPBA 2020 applies.

Therefore, the amendment is, in principle, not be taken into account unless there are exceptional circumstances, which have been justified with cogent reasons by the party concerned.

In the case at hand, auxiliary request 14 had already been submitted with the reply to the appeal, but the appellant waited until the oral proceedings to submit an inventive-step objection based on Table 6.2.1. The board is in agreement with T 2843/19 (Reasons 3.3) that such an objection should have been put forward in reply to the respondent's reply to the appeal for instance in the appellant's letter of 21 July 2022, which does not include said objection either.
There were no new or unforeseen developments in the appeal proceedings and the board cannot see any exceptional circumstances that would justify the objection being taken into account.

It should also be noted that a communication pursuant to Article 15(1) RPBA 2020 does not constitute an

invitation to the parties to make further submissions in reply thereto. (T 995/18, Reasons 1.4).

Therefore, the objection based on Table 6.2.1 of D41 is not taken into account.

8. Article 56 EPC

8.1 Claim 1 now includes that the partition coefficient of the chromatography material for the antibody being greater than 100.

8.2 Points 3.1 to 3.6 remain valid except that Kp>100 is a further differentiating feature with respect to Run 11 of D41.

8.3 The solution to the problem is not obvious for the following reasons:

Table 5.2.1 of D41 shows that the product recovery decreases when the Kp value is in the strong-binding operating mode. While Runs 1 to 11 still have a product recovery of close to 90% or above, Run 12 - which was carried out with a Kp value of 49.2 - only had a product recovery of 79%. Considering Figure 11, which contains the data of Table 5.2.1 (see paragraph [0225] of D41) and the trend for recovery with higher Kp values, it is evident that the skilled person would not consider Kp-values above 100 as suitable alternatives (with respect to recovery) to Kp values of 40 or lower.

Therefore, D41 would not lead the skilled person to Kp>100 in an obvious way.

8.4 Consequently the subject-matter of claim 1 of auxiliary request 14 involves an inventive step. The same applies to claims 2 to 14.

9. Since there were no other objections with respect to auxiliary request 14 from the appellant's side and the board sees no reason to take a different stance in that respect, auxiliary request 14 is allowable.

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 with the order to maintain the patent in amended form on the basis of the claims of auxiliary request 14 filed with the reply to the appeal and a description to be adapted thereto.

The Registrar: The Chairwoman:

C. Vodz S. Besselmann

Decision electronically authenticated