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**Datasheet for the decision
of 17 November 2025**

Case Number: T 1198/23 - 3.3.04

Application Number: 14797310.1

Publication Number: 2997036

IPC: C07K1/22

Language of the proceedings: EN

Title of invention:

Purification of recombinantly produced polypeptides

Patent Proprietor:

Medimmune Limited
MedImmune, LLC

Opponents:

GlaxoSmithKline Intellectual Property
Development Limited
Oetke, Cornelia

Headword:

Purification methods/MEDIMMUNE

Relevant legal provisions:

EPC Art. 54, 100(a), 100(b)
RPBA 2020 Art. 15(3)

Keyword:

Main request - Novelty (yes) - Sufficiency of disclosure (Yes)
Oral proceedings - held in absence of party

Decisions cited:

T 0910/02, T 0663/10, T 0671/12, T 0166/17, T 0245/19,
T 1750/19



Beschwerdekammern

Boards of Appeal

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Case Number: T 1198/23 - 3.3.04

D E C I S I O N
of Technical Board of Appeal 3.3.04
of 17 November 2025

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Decision under appeal: **Decision of the Opposition Division of the
European Patent Office posted on 4 May 2023
rejecting the opposition filed against European
patent No. 2997036 pursuant to Article 101(2)
EPC.**

Composition of the Board:

Chairwoman M. Pregetter
Members: D. Luis Alves
 A. Bacchin

Summary of Facts and Submissions

- I. European patent No. EP 2 997 036, entitled "*Purification of recombinantly produced polypeptides*", was granted on the basis of European patent application No. 14 797 310.1, with seven claims. It claims priority from US patent application 61/823,520, which was filed on 15 May 2013.

Claim 1 of the patent as granted reads as follows.

"1. A method of reducing host cell protein (HCP) level in a composition comprising a recombinantly produced polypeptide, the method comprising:
providing a clarified cell culture supernatant comprising the recombinantly produced polypeptide and one or more HCP;
loading the clarified cell culture supernatant onto a Protein A chromatography column;
washing the Protein A chromatography column with a wash buffer comprising between 50 mM and 100 mM sodium caprylate at a pH between 8 to 9 to remove HCP."

Claims 2 to 7 define further features of the method defined in claim 1.

- II. Two oppositions were filed, invoking grounds for opposition under Article 100(a) EPC in conjunction with Article 54 EPC (lack of novelty) and Article 56 EPC (lack of inventive step) as well as grounds for opposition under Article 100(b) EPC and Article 100(c) EPC.

III. The opposition division rejected the oppositions. Opponent 1 (appellant) filed an appeal against that decision.

The patent proprietors are the respondents in these appeal proceedings.

Opponent 2 is a party as of right.

IV. With the statement setting out the grounds of appeal, the appellant submitted arguments contesting the opposition division's decision in respect of novelty in view of document D1 and sufficiency of disclosure. The appellant did not contest the decision in respect of Article 100(c) EPC or Article 100(a) EPC in relation to inventive step.

V. With the reply to the appellant's statement setting out the grounds of appeal, the respondents filed auxiliary request 1.

VI. The party as of right did not make any substantive submissions during the appeal proceedings.

VII. The board appointed oral proceedings for 21 May 2025. In a communication pursuant to Article 15(1) RPBA dated 21 January 2025, the board informed the parties of its preliminary opinion that the appellant's arguments were not persuasive and that it seemed likely the appeal would be dismissed.

VIII. With letters dated 25 March 2025 and 4 April 2025, respectively, the appellant and the party as of right informed the board that they would not be attending the oral proceedings.

IX. The board then cancelled the oral proceedings.

X. The following documents are referred to in this decision:

D1: WO 2014/141150

D2: US patent application 61/787,309, from which document D1 claims priority

D3: V.S. Stoll and J.S. Blanchard, "Buffers: Principles and Practice", Methods in Enzymology 182, 1990, chapter 4, pages 24 to 38

XI. The appellant's arguments, where relevant to this decision, may be summarised as follows.

Novelty (Articles 100(a) and 54(3) EPC)

Claim 1 was not novel because all of its features were disclosed in combination in document D1 (see page 2, lines 10 to 21, and page 12, line 29, to page 13, line 8). These passages referred to a wash buffer comprising 100 mM sodium caprylate at a pH of "about" 7.5.

However, the term "about" was defined in document D1 to mean $\pm 20\%$ (see page 3, lines 26 to 29). Hence, the passage on page 2 of D1 actually disclosed a range of 6 to 9 for the pH value.

The decision under appeal was wrong when it took the view that $\pm 20\%$ resulted from a selection from multiple error margins corresponding to the term "about", since each narrower error margin was fully encompassed by the preceding broader one. Moreover, no pointer to a

specific error margin was required because when an application specifies error margins they must be read in place of the term "about". Applying the specific error margin of $\pm 20\%$ to the pH value of 7.5 did not present the skilled person with new information.

The decision under appeal was also wrong in concluding that in order to arrive at the wash buffer of claim 1, it was necessary to select caprylate in addition to the specific error margin. Caprylate was one of the aliphatic carboxylates specifically disclosed on page 3 of document D1. Thus, at most, one single selection was necessary: the error margin of 20%.

Additionally, the claimed range of between 8 and 9 for the pH value was not novel because claim 27 of document D1 specified that the wash buffer contained Tris as the organic base, and it was known that a Tris buffer had a pH value of 8.06 (see document D3).

Disclosure of the invention (Article 100(b) EPC)

The method defined in claim 1 was not sufficiently disclosed. The effect of reducing host cell protein was stated in the claim. However, not all embodiments encompassed by the claim achieved this effect and, where they did, there was a lack of reproducibility of the effect. This was demonstrated in Examples 1 and 2 of the patent.

XII. The respondents' arguments, where relevant to this decision, may be summarised as follows.

Novelty (Articles 100(a) and 54(3) EPC)

Document D1 did not directly and unambiguously disclose a wash buffer with a pH of 8 to 9.

The only specific examples of a wash buffer with sodium caprylate had pH values of 7.2 or 7.5. As regards the disclosure of "about pH 7.5", there was no pointer towards selecting an error margin of $\pm 20\%$ to apply to this pH value.

Furthermore, arriving at the buffer of claim 1 required a selection of the $\pm 20\%$ error margin from a list and the selection of caprylate from another list.

Claim 27 of document D1 did not imply a pH value of 8.06. Document D3 merely showed the buffer capacity of the listed buffers and did not show the pH for a wash buffer comprising 50 to 100 mM sodium caprylate, as required by claim 1. The desired pH buffer in document D1 was 7.2 or 7.5. This was therefore what the skilled person carrying out the method of D1 would prepare, even if Tris would be suitable for preparing a buffer at a pH of 8.06. Such a pH was not directly and unambiguously derivable from document D1.

Disclosure of the invention (Article 100(b) EPC)

The effect in claim 1 of reducing the HCP level meant achieving a reduction compared with the level before carrying out the method (see paragraph [0043] of the patent). Such a reduction was demonstrated in Examples 1 and 2 of the patent.

XIII. The parties' requests

The appellant requested that the decision under appeal be set aside and that the patent be revoked in its entirety. Oral proceedings were requested as an auxiliary measure.

The respondents requested that the appeal be dismissed and that the patent be maintained as granted; or, alternatively, that the patent be maintained in amended form on the basis of the claims of auxiliary request 1 as filed with their reply to the appeal. Oral proceedings were requested as an auxiliary measure.

The party as of right, opponent 2, did not make any substantive submissions during the appeal proceedings.

Reasons for the Decision

Decision in written proceedings (Article 116 EPC and Article 15(3) RPBA)

1. The board had summoned the parties to oral proceedings as requested. In its communication pursuant to Article 15(1) RPBA, the board informed the parties that it was inclined to dismiss the appeal. The appellant subsequently indicated, in a letter dated 25 March 2025, that it would not be attending the oral proceedings.
2. In accordance with established case law, if oral proceedings are scheduled as a result of a party's request for such proceedings as an auxiliary measure,

and if that party subsequently states that it will not be appearing at the oral proceedings, such a declaration results in the request for oral proceedings becoming ineffective, and the board may dispense with oral proceedings if no other reason makes it necessary or desirable to hold them (see also T 245/19, Reasons 1, and Case Law of the Boards of Appeal of the European Patent Office, 11th ed., 2025, III.C.5.3.2 b)). Thus, under these circumstances and irrespective of whether or not the appellant explicitly maintains its request for oral proceedings, it is within the discretion of the board to decide whether or not the scheduled oral proceedings are to be maintained or to be cancelled, since it cannot be the purpose of Article 116 EPC that a party can oblige a board to hold oral proceedings in its absence (see T 910/02, point 6 of the Reasons; T 663/10, point 1.3 of the Reasons; T 671/12, point 2 of the Reasons; T 166/17, point 1.2 of the Reasons; T 1750/19, point 2.2 of the Reasons).

3. Since in the present case there was no reason to hold the oral proceedings, the oral proceedings were cancelled, and this decision is taken in written proceedings based on the minutes of the oral proceedings before the opposition division, the decision under appeal, the parties' submissions, the arguments and requests on appeal, and the board's communication under Article 15(1) RPBA in accordance with Article 12(2) and (8) RPBA and Article 113(1) EPC. The dismissal of the appeal (see below) complies with the main request of the respondents. Consequently, the scheduled oral proceedings were cancelled.

Main request (patent as granted)

Novelty (Articles 100(a) and 54(3) EPC) - all claims

4. The appellant relied on the disclosure in document D1. This document is an international patent application filed later than the date of priority claimed by the patent in suit and published on 18 September 2014, which is later than the date of filing of the patent in suit. However, document D1 claims priority from document D2. The date of priority claimed is earlier than the priority date claimed by the patent in suit, which was not contested. Therefore, only the embodiments in document D1 which are entitled to claim priority are to be taken into account for assessing the novelty of the subject-matter of the claims as granted. This is not in dispute between the parties.
5. In the decision under appeal, the opposition division held, *inter alia*, that the disclosure of a wash buffer at a pH of about 7.2 to about 8.0 in claim 29 of document D1 was not prejudicial to the novelty of claim 1 because it could not benefit from the date of priority claimed. Indeed, an equivalent passage was not present in document D2. A wash buffer with a pH of between 8 and 9 was otherwise not directly and unambiguously derivable from document D1.
6. The appellant did not dispute that the priority document D2 does not include a disclosure corresponding to claim 29 of document D1.
7. On appeal, the appellant relied on two lines of argument. The first line of argument refers to the following passages of document D1: page 2, lines 10 to 21, and page 12, line 29, to page 13, line 8. These

two passages are identical and disclose a wash buffer comprising 100 mM sodium caprylate at a pH of about 7.5. However, according to the appellant, "about pH 7.5" is to be read as a pH in the range 6 to 9, due to the definition of "about" on page 3, lines 26 to 29.

8. This passage reads as follows. *"'About' as used herein when referring to a measurable value such as an amount, a temporal duration, and the like, is meant to encompass variations of $\pm 20\%$ or $\pm 10\%$, including $\pm 5\%$, $\pm 1\%$, and $\pm 0.1\%$ from the specified value, as such variations are appropriate to perform the disclosed methods"*.
9. As noted by the opposition division, this passage lists multiple other error margins corresponding to the term "about", such as $\pm 10\%$, $\pm 5\%$, $\pm 1\%$ and $\pm 0.1\%$, from which the reader needs to select $\pm 20\%$. The board agrees with the respondents' argument that applying a margin of $\pm 20\%$ to a pH value is not technically reasonable in the context of the invention, namely that of purifying polypeptides by chromatography, as it would result in a pH range of 6 to 9. The range would thus include acidic to basic pH values. Further, the board notes that the cited passage is not disclosed to be for specific application to pH values.
10. The above notwithstanding, the board considers that the cited passages do not disclose the combination of caprylate and the suggested pH range of 6 to 9, either. It is not directly and unambiguously derivable from document D1 which of the three aliphatic carboxylates listed on page 2 (or the identical passage on page 13) - caprylate, decanoate and dodecanoate - should be combined with this pH range resulting from the

selection of $\pm 20\%$ as the error margin. The board is of the view that two selections are required to arrive at the combination of caprylate with the pH range of 6 to 9 suggested by the appellant.

11. In a second line of argument, the appellant referred to claim 27 of document D1, which reads "*The method of any one of claims 22-26 wherein the organic base is tris base*". According to this argument, the disclosure of a Tris base for the wash buffer implies a pH value of 8.06. The board does not find this argument convincing.

11.1 Firstly, the appellant refers to the disclosure in document D3 of a pKa value of 8.06 for Tris. However, the appellant did not indicate any passage in this document stating that every Tris buffer has a pH value of 8.06. Secondly, the board notes that claim 27 refers back to claim 22, and merely further specifies one of the components of the wash buffer defined in claim 22. Claim 22 in turn defines the wash buffer as comprising an organic acid, an alkaline metal or ammonium salt of the conjugate base of the organic acid, and an organic base. This is consistent with the teaching of document D1 as a whole, that buffers comprising a Tris base and an organic acid may have a pH value of 7.2 or 7.5 (see page 13, lines 13 to 14, page 13, line 19, page 17, line 17, Table 3, column entitled "Wash Buffer"). Thus, wash buffers with the components as defined in claims 22 and 27 of this document do not necessarily have a pH value of 8.06. Thirdly, the conclusion above that more than one selection is required to arrive at the combination of caprylate and the pH value defined in claim 1 also applies here. Claim 27 refers back to claim 22, which in turn refers

back to multiple claims, including claims 6 and 7 listing caprylate, decanoate and dodecanoate.

- 11.2 Accordingly, the second line of argument is not convincing either.
12. In conclusion, the parts of document D1 which are entitled to the priority date claimed from document D2 do not directly and unambiguously disclose a wash buffer "at a pH between 8 to 9", as required by claim 1. Moreover, they do not disclose this feature of the wash buffer in combination with the presence of caprylate. At least for this reason, document D1 is not prejudicial to the novelty of claim 1.
13. In light of the above, there is no need to address the appellant's arguments concerning the disclosure in document D1 of the feature "a clarified cell culture supernatant".
14. The appellant's arguments regarding claims 2 to 7 do not need to be addressed either because claim 1 is novel and claims 2 to 7 are dependent on claim 1.

Disclosure of the invention (Articles 100(b) EPC) - claim 1

15. The appellant argued that the claimed invention does not fulfil the requirements of sufficiency of disclosure because the effect recited in claim 1, i.e. "*reducing host cell protein (HCP) level in a composition*", is not achieved over the whole scope of the claim. Three main lines of argument were submitted, all referring to the experimental results in the patent:

- (i) there are inconsistencies between the conclusions in Examples 1 and 2, whereby in Example 1 it is concluded that all three factors (pH, sodium caprylate and sodium chloride) have a significant effect on the HCP level, whereas in Example 2 this is the case for sodium caprylate only;
- (ii) the HCP removal is not reproducible even within the same example - see runs 3 and 4 in Example 1 (Table 4);
- (iii) the effect recited in the claim should be achieved for a wash buffer as defined in claim 1 versus a control wash buffer. However, Example 2 (Table 9) shows that for 6 out of 9 runs with a wash buffer falling within the definition in claim 1, the effect is not achieved in comparison to run 8, which is taken to be the control wash buffer.

15.1 Claim 1 requires the presence of sodium caprylate. According to both Example 1 and Example 2 of the patent, the buffer with sodium caprylate achieves HCP reduction, and therefore achieves the purpose recited in claim 1. This is not disputed by the appellant. Instead, the appellant referred with respect to line of argument (i) to the results obtained with buffers containing additional components. This line of argument is not convincing, as it is not relevant to the sufficiency of disclosure of the claimed method that additional components of the buffer might lead to an improved reduction of HCP.

15.2 As regards line of argument (ii), the board agrees with the respondents that the variability in the HCP reduction between different runs with the same buffer does not on its own demonstrate that the effect of reducing HCP is not achieved. Despite the fact that runs 3 and 4 of Example 1, which use the same wash

buffer, showed variation in the removal of HCP that was achieved (see Table 4), the results as a whole show with statistical significance that increasing the pH and increasing the presence of caprylate, within the wash buffer definition in claim 1, each independently reduced the HCP levels (see Tables 7 and 8).

- 15.3 The central issue of line of argument (iii) is whether, in order for the method defined in claim 1 to be considered sufficiently disclosed, the patent is required to show a removal of HCP by Protein A affinity chromatography with a wash buffer as defined in the claim, or whether it is required to show an improved removal versus a control buffer, and in this case which control buffer would be the most appropriate.

Claim 1 requires a reduction of the HCP level. In the board's view, this reduction of the HCP level is relative to the process stream that enters the chromatography column. Therefore, claim 1 does not require an improved reduction in comparison to any given prior-art method. This claim interpretation is also consistent with the description (see paragraph [0043] of the patent). Thus, the board is in agreement with the reasoning of the opposition division in point 8.4.1 of the decision under appeal. In conclusion, whether or not the HCP removal achieved in the conditions set out in claim 1, in particular the wash buffer defined in the claim, is improved relative to other buffers is not relevant to the claim at issue. Since the patent shows that the stream exiting the chromatography column contains less HCP than the stream entering the column, with a wash buffer as defined in claim 1 (see point 15.2 above), the patent shows that the HCP is removed in the conditions set out in claim 1.

Conclusion

16. Therefore, the grounds for opposition under Article 100(a) in conjunction with Article 54 EPC (lack of novelty) and the grounds for opposition under Article 100(b) EPC do not prejudice the maintenance of the patent as granted.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairwoman:



I. Aperribay

M. Pregetter

Decision electronically authenticated