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Datasheet for the decision of 1 December 2011

Case Number: T 1021/08 - 3.3.04

Application Number: 96500164.7

Publication Number: 787498

IPC: A61K 39/38

Language of the proceedings: EN

Title of invention:
Therapeutic human albumin having a low aluminium binding capacity

Applicant:
Grifols, S.A.

Opponents:
NHS Blood and Transplant (Gwaed a Thrawsblaniadau'r GIG)
Baxter Aktiengesellschaft
LABORATOIRE FRANCAIS DU FRACTIONNEMENT ET DES BIOTECHNOLOGIES S.A.
Octapharma AG
CSL Behring GmbH
Stichting Sanquin Bloedvoorziening

Headword:
Human albumin/GRIFOLS SA.

Relevant legal provisions:
EPC Art. 83

Keyword:
"Sufficiency of disclosure: undue burden (yes)"

Decisions cited:
T 1621/09

Catchword:
-

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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 1021/08 - 3.3.04

D E C I S I O N
of the Technical Board of Appeal 3.3.04
of 1 December 2011

Appellant: (Applicant)
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Decision under appeal:
Decision of the Opposition Division of the European Patent Office posted 7 March 2008 revoking European patent No. 787498 pursuant to Article 101(3)(b) EPC.

Composition of the Board:

Chairman: C. Rennie-Smith
Members: R. Gramaglia
B. Claes

Summary of Facts and Submissions

I. European patent No. EP-B-0 787 498 (application No. 96 500 164.7) having the title "Therapeutic human albumin having a low aluminium binding capacity" was granted with the following two claims:

"1. A process for preparing a therapeutic human albumin solution derived from Cohn fraction V as a starting material comprising the steps of diafiltration and determining the concentration of citrate to be 0.5 mmol/l or less, preferably to be 0.037 mmol/l or less."

"2. Use of a therapeutic human albumin solution having a low aluminium binding capacity, derived from Cohn fraction V, which has been diafiltered and whose citrate concentration has been determined to be 0.5 mmol/l or less, preferably 0.037 mmol/l or less, for preparing a pharmaceutical preparation acceptable for intravenous administration."

II. Notices of opposition were filed by six opponents (OI to OVI) requesting the revocation of the European patent in view of Articles 100 (a), (b) and (c) on the grounds that the claimed subject-matter lacked novelty and inventive step (Articles 54 and 56 EPC), had not been sufficiently disclosed (Article 83 EPC) and extended beyond the content of the application as originally filed (Article 123(2) EPC).

III. In its decision dated 7 March 2008 the opposition division revoked the patent because claims 1 and 2 of the patent as granted did not fulfil the requirements of Article 83 EPC. The patent proprietor filed a notice

of appeal dated 16 May 2008, paid the appeal fee on the same date and filed a statement of grounds of appeal dated 17 July 2008. The appellant's only request in both the notice and grounds of appeal was to set aside the decision under appeal and to maintain the patent as granted.

IV. Replies to the statement of grounds of appeal were filed by respondents I, II, III and VI (opponents O1, O2, O3 and O6) on 4 February 2009, 8 December 2008, 9 February 2009 and 29 January 2009, respectively. The appellant filed further written submissions dated 4 August 2009 stated to be in response to those replies, respondent II filed further written submissions dated 25 October 2010 stated to be in response to those submissions of the appellant of 4 August 2009, and the appellant filed yet further written submissions dated 21 April 2011 stated to be in response to those of the respondent II of 25 October 2010. On 5 May 2011 the board sent a communication to the parties reminding them of the relevant provisions of the RPBA regarding written submissions.

V. On 28 October 2011 the appellant filed an auxiliary request which it requested the board to admit into the proceedings by exercise of its discretion under Article 13(3) RPBA. On 28 November 2011 the respondent III filed a letter submitting that the auxiliary request should be held inadmissible.

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

D2 More J.E. Et al., Engineering Foundation Conference, Recovery of Biological Products, Poster (1990);

D4 Declaration by Malcolm Beeton dated 14 March 2005;

D6 WO-A-91/00290;

D43 Batch release protocols of albumin preparations produced in 1995 by CLB;

D47 Moellering H., Methods in Enzymatic Analysis, Bergemeyer H.U. editor, VCH Verlagsgesellschaft, Weinheim, Germany, 3rd edition, Vol. VII, pages 2-12 (1985);

Exhibit A Experimental report filed by respondent 2 on 18 March 2005.

VII. The submissions by the appellant (patentee), insofar as they are relevant to the present decision, can be summarized as follows:

Main request
Sufficiency of disclosure

– The skilled person would have understood that only the diafiltration step in Example 1 of the patent in suit (see page 3, line 54) had the potential to reduce the citrate concentration.

– The skilled person would have also understood that the various citrate concentrations depicted at the

left of Table 1 of the patent (0.71 mM, 0.12 mM and 0.037 mM) represented those obtained after varying extents of diafiltration, with the value "0.71 mM" representing a citrate concentration taken from a solution which had not undergone sufficient diafiltration.

– Once the size of the component to be removed, its maximum end concentration and the diafiltration technique as the method of choice were identified, putting the claimed subject-matter into practice was a matter of routine trial and error.

– Based on common general knowledge, the skilled person would modify the diafiltration of Example 1 by subjecting a solution of albumin intended for intravenous administration to diafiltration against an isotonic solution, in order to avoid any change in the ionic concentration of the medium.

– It was already known from document D6 that in order to obtain reduced aluminium in an albumin preparation, diafiltration against a saline solution was the method of choice.

– The experimental tests submitted by respondent OII used purified water. Had respondent OII used an isotonic saline solution as the only diafiltration buffer, which made sense to the skilled person, reduction of citrate to the claimed levels would have taken place.

– The determination of citrate could be made by means of the well established and reliable technique

disclosed in document D47, which was capable of detecting concentration of citrate below 0.05 mM.

– No objection under Article 83 EPC could arise from the misinterpretation of the term "determining" in claim 1, which term was clear and related to the numerical quantification of a state already present rather than influencing this state.

Admissibility of the auxiliary request

– The auxiliary request was filed in case the board should agree with certain of the respondents' objections under Article 123(2) EPC to the main request. The board did not provide a preliminary opinion with the summons to oral proceedings and, in the absence of such an opinion, the appellant had a responsibility to address issues which might be raised. To safeguard its rights it had filed a request dealing with the most obvious issues under Article 123(2) EPC. The purpose of the RPBA was to ensure no party is surprised. The auxiliary request was filed over one month before the oral proceedings which gave the respondents sufficient time to consider its two claims. One reason this request was not filed in the opposition proceedings was that the appellant wanted to read the reasons for the opposition division's decision before filing any auxiliary requests.

VIII. The submissions by the respondents (opponents) can be summarized as follows:

Main request

Sufficiency of disclosure

– There was no disclosure in the patent in suit of any link between diafiltration and the lowering of the citrate concentration. Paragraphs [0013] and [0023] of the patent related to diafiltration in the context the reduction of the aluminium and ethanol concentrations. Paragraph [0023] would rather lead the skilled person to assume that diafiltration was not suitable for reducing citrate concentration.

– Exhibit A annexed to the respondent OII's submission dated 18 March 2005 showed that when the common general knowledge was used, diafiltration did not result in the low citrate concentrations specified in claim 1.

– It could not be derived from Example 1 and Table 1 (see "0.71 mM", "0.12 mM" and "0.037 mM") of the patent that the three samples were the result of diafiltration with increasing length of time.

– The fact that the final therapeutic product had to be isotonic did not imply that the albumin-containing sample had to be isotonic throughout the whole process. Hence, there was no teaching in the patent that the diafiltration solution had to be isotonic.

– The patent in suit did not specify how the citrate concentration had to be measured, and the result could vary by a factor of two, depending on the measurement method.

– The term "determining" in claim 1 could relate either to a step of "measuring" or to a step of "adjusting" the concentration of citrate. In the latter case, the patent did not provide any information as to how to adjust the citrate concentration within the claimed values.

Admissibility of the auxiliary request

– The respondents argued that the auxiliary request be rejected as late filed. The case law showed that amendments to patent documents should be filed at the earliest moment in appeal proceedings and may be disregarded if not submitted in good time prior to oral proceedings. In the present case the request was filed only about one month before the oral proceedings although the objections it addressed were known to the appellant for over three years, at latest when it received the replies to the statement of the grounds of appeal. When filing the request the appellant made no attempt to justify the lateness nor did it sufficiently substantiate the allowability of the request. Although stated to address certain objections under Article 123(2) EPC, nothing was said about sufficiency of disclosure, the ground on which the patent was revoked, so the auxiliary request was not clearly allowable.

IX. The appellant (patentee) requested, as main request, that the decision under appeal be set aside and the patent be maintained as granted or, as auxiliary request, that the patent be maintained on the basis of

the auxiliary request as submitted with letter dated 28 October 2011.

The respondents (opponents O1 to O6) requested that the appeal be dismissed and those respondents present at the oral proceedings requested that the auxiliary request filed with the appellant's letter dated 28 October 2011 be held inadmissible.

Reasons for the Decision

Written submissions

1. In the present case both the appellant and respondent II filed additional written submissions after, respectively, filing their statement of grounds of appeal and replies (see paragraph IV above). In the appellant's case, there were two additional submissions. The only written submissions which are necessarily taken into account are those referred to in Article 12(1) RPBA (to the extent they are relevant and comply with Article 12(2) RPBA - see Article 12(4) RPBA), namely an appellant's notice and statement of grounds of appeal and the respondents' replies, each of which should contain a party's complete case (see Articles 12(1)(a)(b) and 12(2) RPBA). Any other submissions, unless answering a communication from the board (see Article 12(1)(c) RPBA and again subject to Article 12(4) RPBA), are amendments to a party's case and admissible only at the board's discretion (see Article 13(1) RPBA). No explanation was given for filing any of the late submissions and none of the

parties concerned made any request for leave to amend its case thereby.

2. The cited provisions of the RPBA quite clearly foresee only one written submission from each party supplemented as necessary by answers to communications (if any) from the board. They do not foresee, and there is no right to, responses to the reply or any further exchanges of written submissions. Indeed the current RPBA were intended *inter alia* to prevent such "ping pong" submissions (see the full summary of the legislative history in T 1621/09 of 22 September 2011, points 25 to 34). While the board was able to decide the present case without needing to decide on their admissibility, such additional written submissions beyond those envisaged by the RPBA add to the work of the board (and the parties), tend to delay appeal proceedings, and could be the subject of costs orders under Article 16(1) RPBA.

Main request
Sufficiency of disclosure (Article 83 EPC)

3. It stated in the patent in suit that citrate is the agent responsible for the increase in aluminium content over time in therapeutic albumin solutions stored in glass, and that the removal of this citrate down to a specific level below 0.5 mM, preferably less than 0.037 mM, the latter being the detection limit (see page 4, lines 39-40 of the patent) is desirable for lowering aluminium release from the glass container upon storage.

4. In order to carry out the process according to claim 1 and put into practice the medical use according to claim 2, the skilled person has to lower the citrate concentration in the therapeutic human albumin solution to the desired level.

5. Therefore, the question arises whether or not the technical information provided by the patent in suit, supplemented by common general knowledge, enables the average skilled person to arrive at levels of citrate below 0.5 mM, preferably less than 0.037 mM, without undue burden of experimentation.

6. As regards the technical information provided by the patent in suit, the respondents argue that the skilled person could not derive from the patent any causal relationship between the lowering of the citrate concentration and diafiltration, whereas the appellant denies this contention by relying on the passages on page 2, lines 55-57 and page 3, lines 25-30 and on Example 1 (in particular on page 3, lines 54 and 58 and page 4, line 4 ("citrate concentrations obtained") and line 7 ("final citrate concentration")) of the patent.

7. It is stated in the patent in suit on page 2, lines 55-57 that diafiltration removes excess salts, aluminum and ethanol, including "low-molecular-weight compounds" and that citrate is always present in Cohn fraction V used as the starting material in the albumin preparation method (see page 3, lines 25-30 of the patent in suit). Thus, in the board's view, these two passages cited by the appellant merely confirm that diafiltration was useful to remove the "low-molecular-weight compounds", without pointing to diafiltration as

the method of choice to reduce the citrate concentration to trace levels. Diafiltration is also referred to in paragraphs [0013], [0015] and [0023] of the patent, however, this is done in the context of the reduction of the aluminium and ethanol concentrations. It is also stated in paragraph [0023] that despite the the solution of the starting albumin fraction V had been diafiltered to eliminate the aluminium to the extent of values of less than 200 ppb and even 50 ppb or less, a citrate contamination exceeding the value of 1 mmol/liter (1 mM) persisted. This passage of the patent would thus rather lead the skilled person to assume that diafiltration was not suitable for further reducing citrate concentration below 1 mM.

8. The appellant also relies on Example 1 of the patent, in particular on page 3, lines 54 and 58 ("[A]fter diafiltration ....the concentration of each batch was determined") and on page 4, lines 4 and 7 ("[T]he citrate concentrations obtained" and "final citrate concentration") for arguing that the patent made it clear that diafiltration was the only step responsible for lowering the citrate concentration.

9. However, while the cited passages of Example 1 mention diafiltration, this is done in combination with other steps, such as the "adjustment to 20% protein concentration" (see page 3, line 54 of the patent).

10. The board is of the opinion that the skilled person could reasonably assume that some additional steps, such as e.g. the addition of water for adjusting the protein concentration to 20%, might have altered the citrate concentration. The appellant argues that the

skilled person would have performed such adjustment such that only the albumin concentration changed, while all the other solutes remained constant. In the board's view, however, keeping the concentration of all the other solutes constant would have necessarily implied adding a solution containing citrate, when the scope of the invention was its removal, which would not make sense.

11. A further line of argument of the appellant was that the skilled person would have considered that the three batches having different citrate concentrations on the left of Table 1 of the patent (0.71 mM, 0.12 mM and 0.037 mM) were the result of diafiltration with increasing length of time, with the value "0.71 mM" representing too short a diafiltration.

12. However, it cannot be derived from the patent -either explicitly or implicitly - that the three samples were treated differently. Rather, the fact that measurement of the citrate concentration took place after 14 days and 10 hours (see page 3, line 57 of the patent) does not suggest a diafiltration where the citrate concentration was measured at different times for each sample.

13. Moreover, the board observes that Example 1 fails to provide any information as to the citrate concentrations prior to diafiltration. The appellant admitted in paragraph 4.2 of its Grounds of Appeal that the amount of citrate initially present will be different from sample to sample. Without this information the skilled person could not deduce that a reduction of the citrate concentration had taken place.

Rather, he/she was taught by Table 1 of the patent that the same process described in Example 1 apparently yielded three batches having different citrate concentrations, one of which (0.71 mM) did not reach the claimed upper limit of 0.5 mM. The reasons for this failure were not evident to the skilled person. In view of this further uncertainty, the skilled person could not unambiguously conclude that the diafiltration step in Example 1 was responsible for the decrease, if any, in citrate concentration. The skilled person could also not exclude that techniques for citrate reduction alternative to diafiltration had been used, such as chromatography or washing the albumin solution with water and concentrating on an Amicon® or Millipore® cut-off filter.

14. In conclusion, it is the board's view that no causal relationship can be derived from the disclosure in the patent in suit between the lowering of the citrate concentration and the diafiltration step mentioned on page 3, line 53. As a consequence, the skilled person was not in a position to reproduce any of Examples 1 to 3 of the patent in suit, the more so as no indication was given under which conditions (pH, buffers, volumes, time, cut-off, etc.) diafiltration had to be carried out.

15. As regards performing the claimed process on the basis of the patent supplemented by common general knowledge, the appellant argues that once the size of the component to be removed, its maximum end concentration and the diafiltration technique as the method of choice were identified, putting the claimed subject-matter into practice was a matter of routine trial and error.

In other words, in the appellant's opinion, the skilled person would modify the diafiltration step referred to in Example 1 of the patent (see page 3, line 53 et seq.) by subjecting a solution of albumin intended for intravenous administration to diafiltration against a solution isotonic with human blood (corresponding to 150 mM NaCl), in order to avoid any change in the ionic concentration of the solution, and automatically arrive at levels of citrate below 0.037 mM.

16. In support of this contention, the appellant refers to the BPL product label in Annex MB-2 of document D4, which shows that the final therapeutic albumin solution comprises 145 mmol/l sodium (see the BPL product label) and document D43 (see under "CLB Product Division/Finished Product Specification No. SE H2200-101/5, point 7.9.1: "sodium 130-160 mmol/l"). The appellant also points out that it was known from document D6 (see page 9, lines 17-18) that in order to obtain reduced aluminium in an albumin preparation, diafiltration against a saline solution was the method of choice.

17. However, in the board's judgement, only the final therapeutic product needs to be isotonic. This does not necessarily imply that the albumin-containing solution needs to be kept isotonic throughout the whole purification process. In fact, there is no suggestion in the patent in dispute, nor in the prior art, that the albumin-containing sample should be kept isotonic throughout the whole process. Rather, page 3, line 40 and page 4, line 35 of the patent ("the albumin solution is adjusted to be stable and isotonic" and "final albumin adjusted by...and isotony (sodium

chloride)") suggest that NaCl should be added at the end of the whole albumin preparation process. If the solutions had been already isotonic, as the appellant maintains, there would be no need for them to be "adjusted to be ...isotonic". Moreover, document D2 (see the first paragraph under the heading "The ion exchange chromatographic process") shows that pyrogen free water (PFW) was a perfectly suitable diafiltration solution.

18. Assuming, for the sake of hypothesis, that paragraph [0023] of the patent would have suggested to the skilled person that the diafiltration processes for removing the aluminium of the prior art were too short for removing citrate (the concentration of which remained > 1mM), he/she would have tried to perform diafiltration more exhaustively. However, in view of the "final" adjustment of isotony highlighted in point 17 supra and the absence in Example 1 of any hint about the addition of NaCl during diafiltration, the skilled person could have reasonably used water without any addition of salt as the diafiltration buffer. But no reduction of the citrate concentration below 0.037 mM would have taken place, as shown by Exhibit A filed with the respondent 2's submission dated 18 March 2005. The latter is an experimental report about a comparison of citrate reduction in albumin under different diafiltration conditions. Experiment 1 of Exhibit A, involving only water as the diafiltration buffer failed to reduce the concentration of citrate below 0.99 mM (see "Results").

19. Finally, the appellant argues that paragraph [0025] of the patent explicitly teaches the skilled person that

citrate associated strongly to albumin and that this association could be disrupted in the presence of an ionic charge (hence the necessity of using saline solutions), liberating the citrate for removal by an appropriate method such as diafiltration.

20. However, in the board's opinion, paragraph [0025] of the patent does not address the problem of reducing the concentration of citrate but rather provides a tentative explanation (see the expressions ""not well known at present" and "is assumed") of the possible mechanism underlying the aluminium release from the glass, postulating the existence of an albumin-citrate complex, which complex could be dissociated by an "ionic charge". Furthermore, the fact that citrate associated strongly to albumin was known to the inventors of the patent in suit only (who used 0.25 M NaCl to dissociate it; see point 23 infra), not to the skilled person reading the patent.

21. Therefore, in the board's view, the skilled person would have taken paragraph [0025] with caution, or at most as an invitation to investigate experimentally how (and how strongly) citrate interacted with albumin. As admitted by the appellant during the oral proceedings, elucidating the nature of the albumin-citrate complex (electrostatic, lipophilic, etc.) was a prerequisite to design a method for its removal. It was critical for the skilled person to establish how it could be dissociated and/or which counter-anion could displace citrate from the complex, given that all this information was missing in the patent in suit.

22. It is true that the prior art referred to an albumin-aluminium complex, from which aluminium could be displaced by means of a monovalent metal ion (see Example 1 of document D6, read in combination with page 4, lines 3-6 of the same document, and paragraph [0014] of the contested patent, referring to "ionic displacement" in the prior art techniques. But even if the skilled person had combined the teaching of document D6 with the suggestion made in paragraph [0025] of the patent, difficulties could have arisen because citrate was not a multivalent metal ion but, depending on the pH, a multivalent anion of an organic tricarboxylic acid. Moreover, selecting the "ionic" diafiltration route implied that the skilled person had to proceed against the teaching provided on page 3, line 40 ("adjusted to be ...isotonic") and page 4, line 35 ("adjusted by... isotony (sodium chloride)" that ions had to be added only at the end of the whole albumin preparation process.

23. Finally, even if the skilled person used an isotonic solution (150 mM NaCl) as a diafiltration buffer, as the appellant maintains, doubts arise that he/she could reach the citrate concentration limit of 0.037 mM within reasonable time lags, especially in the case of highly concentrated albumin solutions. This is because there is evidence before the board (see the paragraph bridging pages 4 and 5 of the submission dated 6 November 2000 by the then applicant) that the inventors of the patent in suit in reality made use of a 250 mM NaCl solution as a diafiltration buffer. This critical technical information is missing in the patent in dispute.

24. In conclusion, the patent in suit provides no details which could facilitate the repetition of the work. On the contrary, owing to its numerous omissions, the skilled person relying on the information given in the patent, whether supplemented by common general knowledge or not, would not have achieved the desired final goal. Hence, the only alternative left was to ascertain the information missing in the patent by a thorough investigation -undue for an average skilled person- aimed at finding out the parameters (pH, which ions, ionic force, run time, albumin concentration) under which it could be possible to reduce citrate to trace levels. Thus, the requirements of Article 83 EPC are not satisfied.

Admissibility of the appellant's auxiliary request

25. The main request having been found not to meet the requirements of Article 83 EPC, the board considered the admissibility of the auxiliary request filed on 28 October 2011. The appellant submitted in its letter of that date that the auxiliary request dealt with objections of the respondents under Article 123(2) EPC and indeed the request appears to have been limited to addressing those objections. Thus the respondents' submission that it did not address the issue of sufficiency of disclosure under Article 83 EPC appears correct. Therefore the auxiliary request would not have assisted the appellant and, apart from any other considerations such as the filing of the request at a very late point in the appeal proceedings and the fact that it could have been but was not filed in the first instance proceedings, no purpose would have been served by admitting it into the proceedings.

26. The only substantive issues dealt with in the decision under appeal were those of Article 123(2) EPC and 83 EPC. In view of the negative conclusions arrived at by the board in respect of sufficiency of disclosure (see point 24 supra), no need arises for the board to deal with Article 123(2) EPC.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

P. Cremona C. Rennie-Smith