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Datasheet for the decision of 7 December 2011

Case Number: T 1828/08 - 3.2.02

Application Number: 94101963.0

Publication Number: 605395

IPC: A61M 1/16, B01F 5/10

Language of the proceedings: EN

Title of invention:

Apparatus and method for preparation of a fluid intended for medical use

Patentee:

Gambro Lundia AB

Opponent:

Fresenius Medical Care Deutschland GmbH

Headword:

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Relevant legal provisions:

EPC Art. 56, 76(1), 100(a)(b)(c), 114(1)(2), 123(2) RPBA Art. 12(1)(4), 15(2)

Keyword:

"Extended subject-matter: yes (main request) - no (first auxiliary request)"

"Admissibility of late-filed evidence (no)"

"Postponement of oral proceedings: no"

Decisions cited:

G 0009/91, G 0010/91, G 0001/95

Catchword:

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[&]quot;Inventive step: yes"



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Boards of Appeal

Chambres de recours

Case Number: T 1828/08 - 3.2.02

DECISION

of the Technical Board of Appeal 3.2.02 of 7 December 2011

Appellant: Fresenius Medical Care Deutschland GmbH

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Decision under appeal: Interlocutory decision of the Opposition

Division of the European Patent Office posted 15 July 2008 concerning maintenance of the European patent No. 605395 in amended form.

Composition of the Board:

Chairman: P. L. P. Weber
Members: C. Körber

A. Pignatelli

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Summary of Facts and Submissions

- I. On 15 July 2008 the Opposition Division posted its interlocutory decision concerning maintenance of European patent No. 605395 in amended form.
- II. An appeal was lodged against this decision by the opponent (appellant), by notice received on 23 September 2008, with the appeal fee being paid on the same day. The statement setting out the grounds of appeal was received on 25 November 2008.
- III. By communication of 26 September 2011, the Board summoned the parties to oral proceedings scheduled for 7 December 2011 and forwarded its provisional opinion to them on 7 October 2011.
- IV. The appellant's representative requested, by letter dated 10 October 2011, that the oral proceedings be postponed because he had been previously summoned to oral proceedings before the EPO in The Hague on 8 December 2011. By communication of 13 October 2011, the Board indicated that no statement was filed why the appellant's representative could not be substituted by one of the other representatives of his association of representatives. Moreover, the oral proceedings in The Hague were not scheduled for the same day as in the present case. Since no submissions were submitted on these issues, the preconditions which would allow the Board to grant the request for postponement of the oral proceedings pursuant to Article 15(2) RPBA and the Notice of the Vice-President of Directorate-General 3 dated 16 July 2007 concerning oral proceedings before the boards of appeal of the EPO (OJ EPO 2007, Special

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Edition No. 3, 115) were not fulfilled, and the scheduled date for the oral proceedings was maintained.

By letter of 18 October 2011, the patentee (respondent) indicated that he would not be represented at the oral proceedings.

- V. Oral proceedings were held on 7 December 2011.
- VI. The requests of the parties were as follows:

The appellant requested that the decision under appeal be set aside and that the patent be revoked.

The respondent requested that the appeal be dismissed and that, as a main request, the patent be maintained as upheld by the Opposition Division, or on the basis of the sets of claims filed as first to third auxiliary requests with letter dated 6 April 2009.

VII. The following documents are of importance for the present decision:

D1: US-A-4 664 891

D2: D. Schleipfer (Hrsg.): "Dialysetechnik",

Gesellschaft für angewandte Medizintechnik m.b.H.

& Co. KG, Fiedrichsdorf (1988), pages 176 and 184

D7: DE-A-34 43 911

D8: EP-B-0 121 085.

VIII. Claim 1 of the main request reads (with the feature denotation proposed in the statement of grounds of appeal being inserted in brackets):

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"Method for preparation of a fluid intended for medical use, for example dialysis fluid or replacement fluid for hemofiltration or a concentrate for preparation of such fluids, comprising the steps of: providing:

- [a] a source (la) of water and a mixing vessel (21a) containing a powder which is to be dissolved in said water for preparation of the desired fluid,
- [b] means for conducting the water to said mixing vessel (21a),
- [c] a recirculation circuit (20a) including this mixing vessel (21a) and
- [d] means (22a) for recirculation of the water or partially prepared fluid through said mixing vessel (21a)
- [e] supplying water from said source (la),
- [f] after ending supplying water from said source (la) recirculating the water or partially prepared fluid through said mixing vessel,
- [g] monitoring (23a) the concentration in the partially prepared fluid in said recirculation circuit of said powder dissolved in the water, by monitoring the conductivity of the partially prepared fluid in said recirculation circuit, and
- [h] stopping the recirculation when an appropriate concentration is reached from the complete dissolving of the powder."

First auxiliary request

Claim 1 of the first auxiliary request corresponds to claim 1 of the main request with the phrase "in said recirculation circuit," being inserted after the words "by monitoring," in feature [g].

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Claim 9 of both requests reads:

"9. Apparatus for preparation of a fluid intended for medical use, for example dialysis fluid or replacement fluid for hemofiltration or a concentrate for preparation of such fluids, including a source (la) of water and mixing vessel (21a) containing a powder which is to be dissolved in said water for preparation of the desired fluid, comprising means for conducting the water to said mixing vessel (21a), a recirculation circuit (20a) including this mixing vessel (21a), a valve for disconnecting the recirculation circuit from said source of water, means (22a) for recirculation of the water or partially prepared fluid through said mixing vessel (21a) and means (23a) for monitoring the concentration in the partially prepared fluid within the recirculation circuit (20a), of said powder dissolved in the water, for terminating the recirculation when an appropriate concentration is obtained from the complete dissolving of the powder, said monitoring means being in the recirculation circuit."

Claims 2 to 8 and 10 to 19 are dependent claims.

IX. The appellant's arguments are summarised as follows:

The subject-matter of claims 1 and 7 of the main request extended over the content of the parent application as originally filed. Claim 1 failed to specify where the monitoring of the concentration took place. Accordingly, the monitoring could also be performed outside the recirculation circuit, e.g. on

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samples taken therefrom, but this possibility was not disclosed in the parent application as filed. Furthermore, feature [f] of claim 1 did not define that the water supply was stopped by means of a valve, this being the only possibility disclosed in the parent application. Similarly, feature [h] failed to define that the recirculation was stopped by switching the three-way valve 43 for conducting the fluid out of the recirculation circuit. Finally, in the only concrete embodiment of the parent application the mixing vessel 21a was connected to the recirculation circuit via quick-release connectors 59a. Since the uncoupling step of claim 7 did not mention such connectors, it also extended beyond the parent application. The Opposition Division should not have disregarded this latter objection as late filed and not prima facie relevant.

D7 was filed in reaction to the negative preliminary opinion of the Opposition Division with respect to the teaching of D2. Contrary to what was stated in the impugned decision, D7 was indeed prima facie relevant since it clearly taught that conductivity was monitored by sensors 30, 32 during recirculation, and that the circulation was stopped when the salt was completely dissolved in the water.

D8 was filed with the statement of grounds of appeal as a direct reaction to the impugned decision. It disclosed a recirculation circuit wherein concentrate and water were mixed. This circuit comprised a conductivity sensor 17 for monitoring the concentration of the liquid. Accordingly, the subject-matter of claim 1 was rendered obvious from D7 in view of D8.

In addition to features [a] to [e] of claim 1 of the main request, D1 also disclosed features [f] to [h]. From lines 16 to 22 of the abstract it was clear that the fluid was recirculated between the drum and the tank which recirculation was to be continued until the powder had completely dissolved. If the claim was to be construed in such a way that the monitoring of the conductivity actually took place in the recirculation circuit, this possible difference over D1 did not involve an inventive step. The underlying problem was to determine whether the powder had completely dissolved in order to avoid that fluid not yet ready for use was pumped off (which could happen in D1 where this took place after a fixed time interval). However, in view of his general technical knowledge, the skilled person would immediately recognise that the conductivity would then have to be monitored in the recirculation circuit. Additionally, Figure 7.2.1.1 of D2 showed a conductivity monitor located in a recirculation circuit ("Ringleitung"). It was further disclosed that this monitoring served to control the homogeneity of the mixture. Accordingly, it was obvious to the skilled person to monitor the conductivity of the fluid in the recirculation circuit in order to determine whether the fluid was ready for use when taking into account the teaching of D2.

X. The respondent's arguments are summarised as follows:

The fact that the Opposition Division had raised an objection under Article 100(c) EPC should not render it allowable for the opponent to later submit completely new allegations of unallowable added-subject matter not at all related to any amendment by the proprietor. The

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Opposition Division should therefore not have admitted these objections into the proceedings. In accordance with G 10/91 (OJ EPO 1993, 420), these were new grounds of opposition which may not be introduced on appeal without the consent of the proprietor.

The Opposition Division was correct in deciding not to admit the opponent's objection under Article 76(1) EPC against claim 7. Should the Board nevertheless consider that this objection was highly relevant, it was requested that the case be remitted back to the Opposition Division for consideration of this point.

Claim 1 of the main request clearly mentioned "monitoring the conductivity of the partially prepared fluid in said recirculation circuit" and thus specified that the monitoring took place in the recirculation circuit, this being the grammatically most sensible interpretation of claim 1. In any case, the respective amendment introduced in the first auxiliary request made this abundantly and explicitly clear. Although the preferred embodiment utilised valves for stopping the water supply, such valves were nowhere described as being essential, but merely indicated as one "suitable arrangement" for controlling the water supply. Similarly, the use of a three-way valve 43 for conducting the fluid out of the recirculation circuit was merely a practically preferable way of embodying the invention. Finally, there was no need to mention the quick-release connectors in claim 7 since the parent application made it explicitly clear that this construction was preferable and that the exact form of the construction was not essential and could be varied.

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D7 was not to be admitted into the appeal proceedings on the simple basis that it was filed late and was not a legitimate response to an unforeseeable change in the proceedings. Moreover, D7 was not prima facie relevant since it related to a "dumping" system and the conductivity sensors were only used to ensure that there were no differences in conductivity between the top and the bottom of the tank and not for initiating any stopping of recirculation. The late filing of document D8 seemed to be an attempt to have the Board consider a different factual framework than the Opposition Division and was not a legitimate response to any amendment made by the proprietor. The arguments based on a combination of D7 with D8 were, de facto, a brand new opposition. D8 should have already been cited in the first instance proceedings. If D7 and D8 were admitted, it would be appropriate to remit the case to the first instance. Furthermore, D8 was not prima facie relevant since it related to the further dilution of a liquid concentrate and also failed to disclose the key feature of the invention, i.e. the monitoring the concentration and stopping the recirculation when an appropriate concentration was reached.

The problem to be solved by the distinguishing features [f] to [g] of claim 1 over D1 was to make the preparation of the dialysis fluid more efficient. The problem formulated by the appellant contained a pointer to the solution, which was not allowable. D2 disclosed a different species of dialysis fluid preparation ("dumping") than D1 which utilised recirculation. The skilled person was therefore not motivated to refer to D2 when seeking to make D1 more efficient. Figure 7.2.1.1 of D2 showed a spoonful of powder being dumped

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into a tank comprising a mechanical stirring device. The word "umpumpen" simply meant to mix within the tank, and no recirculation outside of the tank was disclosed in D2. D2 disclosed a one-off conductivity check that was carried out on a batch of withdrawn liquid, which was not the same as "monitoring". D2 also failed to teach any method for determining when to stop a recirculation and any link between the checking step and any stopping of a recirculation.

Reasons for the Decision

- 1. The appeal is admissible.
- 2. Main request
- 2.1 Fresh ground for opposition

The opponent's original opposition was based exclusively on the ground of lack of inventive step under Article 100(a) EPC. The opponent did not include any objection under Article 100(c) EPC. However, in its communication dated 6 October 2005, the Opposition Division introduced a new ground of opposition under Article 100(c) EPC and raised an objection under Article 123(2) EPC against claim 1 as granted. Under Article 114(1) EPC the Opposition Division was entitled to raise this ground of opposition of its own motion (see G 9/91, OJ EPO 1993, 408; point 16 of the Reasons). Under these circumstances, the ground of opposition under Article 100(c) EPC does not represent a "fresh ground of opposition" as defined in G 9/91 (see also G 1/95, OJ EPO 1996, 615; point 5.4 of the

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Reasons and "Case Law of the Boards of Appeal of the EPO", 6th Ed. 2010, VII.D.3.2.3a)).

Article 100(c) EPC refers to the extension of subjectmatter beyond the application as filed (cf. Article 123(2) EPC) or, in case of divisional applications, beyond the content of the earlier application as filed (cf. Article 76(1) EPC). Nevertheless, G 1/95 (point 4.2 of the Reasons) makes it clear that the ground for opposition under Article 100(c) EPC (as well as under Article 100(b) EPC) relates to a single legal basis on which an opposition can be based (in contrast to the collections of different legal bases or grounds of opposition defined in Article 100(a) EPC). Accordingly, the objections raised by the opponent under Article 76(1) EPC in the opposition proceedings do not represent "fresh grounds for opposition". Furthermore, they can be considered in appeal proceedings without the approval of the patentee since, according to G 9/91 (point 18 of the Reasons), such approval is only required for fresh grounds introduced at the appeal stage. The respondent's above-mentioned objections (see first paragraph of point X) were, however, already raised during the opposition proceedings.

2.2 Amendments

Feature [g] of claim 1 refers to "monitoring the conductivity of the partially prepared fluid in said recirculation circuit". This wording merely requires that the partially prepared **fluid** is located in the recirculation circuit, but leaves it open where the monitoring actually takes place. The Board does not

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follow the view of the Opposition Division and the respondent that this formulation implies that the monitoring takes place in the recirculation circuit. The term "in the recirculation circuit" grammatically refers back to the term "partially prepared fluid", which immediately precedes it, rather than to the previously used term "monitoring the conductivity". The claim thus fails to specify where the monitoring takes place. Accordingly, the monitoring could also be performed outside the recirculation circuit, e.g. on samples taken therefrom, but this possibility is not disclosed in the parent application as filed. On the contrary, the relevant embodiments shown in Figures 5a and 5b of the parent application both depict the conductivity meter 23a being located in the recirculation circuit 20a, as also stated in the respective text passage in column 7, lines 26 to 29, and in claim 5. As explained in further detail below (see point 3.4) the Board is of the opinion that it is essential for the function of the invention that the monitoring takes place in the recirculation circuit.

Accordingly, the subject-matter of claim 1 of the main request extends beyond the content of the parent application as originally filed in breach of Article 76(1) EPC.

- 3. First auxiliary request
- 3.1 Amendments
- 3.1.1 The Board does not share the appellant's view that feature [f] of claim 1 should mention that the water supply is ended using a **valve** in order to comply with

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the requirements of Article 76(1) EPC. Although the preferred embodiment disclosed in the description of the parent application as filed utilises valves, such valves are nowhere described as being essential, nor are they indispensable for the function of the invention. As correctly stated by the appellant, valves are not the only known means for stopping the water supply. Indeed, lines 17 to 25 of column 3 of the parent application indicate that a valve is merely one suitable arrangement for controlling the water supply. The skilled person was aware that other means could also be used. A further indication that valves are not essential is given by the fact that claim 1 of the parent application as originally filed does not mention any valves. It rather covers valves as one possibility within the broad "means for conducting the water to a mixing vessel".

- 3.1.2 For reasons analogous to those indicated supra, the Board also does not follow the appellant's argument that feature [h] of claim 1 should specify that the recirculation is stopped by switching a three-way valve for conducting the fluid out of the recirculation circuit in order to comply with the requirements of Article 76(1) EPC. Again, such a valve is merely a practically preferable way of embodying the invention. Using a valve for this purpose is not indispensible for the function of the invention, and there is nothing in the parent application as filed that describes this feature as essential.
- 3.1.3 Finally, there is no need in claim 7 for defining that the uncoupling step is performed with quick-release connectors. Lines 40 to 46 of column 4 and lines 39

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to 48 of column 7 of the parent application make it explicitly clear that quick-release connectors are merely preferable. The fact that the mixing vessel is thereby quickly exchangeable is of no relevance for the functioning of the invention.

- 3.1.4 For the above reasons, the appellant's objections under Article 100(c) EPC with respect to the first auxiliary request are not justified. The Board is satisfied that the requirements of Articles 76(1) and 123(2) EPC are met.
- 3.2 In view of the above finding, the question whether the Opposition Division properly exercised its discretion under Article 114(2) EPC not to admit the opponent's objection addressed under point 3.1.3 supra can be left aside. Also, it is not necessary for the Board to deal with the respondent's request to remit the case if this objection is regarded as prima facie relevant and thus discussed at the appeal stage.
- 3.3 Late filed evidence

3.3.1 Document D7

Document D7 was filed late at the opposition stage, namely one month before the oral proceedings before the Opposition Division held on 27 March 2007. Its submission cannot be seen as a response to an unforeseeable claim amendment. It rather represented a reaction to the negative preliminary opinion on inventive step previously expressed by the Opposition Division. In the impugned decision, the Opposition Division found that this document was prima facie not

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more relevant than any of the documents D1 to D6 and thus decided not to admit D7 into the proceedings. Since this discretionary decision has been challenged by the appellant, the Board has to decide whether the department of first instance has exercised its discretion properly. It is not the function of the Board to review all the facts and circumstances of the case as if it were in the place of the department of first instance, and to decide whether or not it would have exercised such discretion in the same way as the department of first instance did.

In the present case, the Board has no doubts that the department of first instance has properly exercised its discretion under Article 114(2) EPC. The issue has been addressed by both parties during the oral proceedings held on 28 May 2008 (see points 4 to 7 of the Minutes), and the criterion taken into account by the Opposition Division, viz. prima facie relevance for the outcome of the proceedings, constituted the right and well-established principle in such a situation.

Consequently, it cannot be said that the discretion was misused or exercised according to the wrong principles or in an unreasonable way. Accordingly, the Board sees no reason to overrule the Opposition Division's decision not to admit D7.

The Board further observes that D7 does not relate to a recirculation circuit as defined in the claims. It rather describes the measurement of concentration with conductivity sensors (30, 32) within a tank (10) comprising an aperture (50) into which salts are "dumped". The two sensors of D7 are primarily included to determine the point when a homogenous mixture has

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been obtained rather than the point when complete dissolving of the salts has been reached.

3.3.2 Document D8

D8 was exclusively cited to challenge inventive step of the subject-matter of claim 1 by combining D7 and D8. No line of argument was presented on the basis of D8 alone or starting from D8 as closest prior art, so that the admittance of D8 can only be decided in combination with that of D7. Since D7 was correctly excluded from the proceedings as detailed supra, the appellant's line of argument based on D7 in combination with D8 cannot succeed for this reason alone.

Pursuant to Article 12(1) RPBA the appeal proceedings shall in principle be based on the notice of appeal and the statement of grounds of appeal. D8 was filed with the appellant's statement of grounds of appeal. However, the Board does not accept the appellant's argument that D8 was filed as a "direct reaction" to the Opposition Division's decision. This decision can hardly be seen as surprising given the preliminary opinion previously issued by the Opposition Division. Also, the respondent did not amend the claims during the oral proceedings held on 28 May 2008, and so no change in the subject of the proceedings can be recognised that would cause the filing of new prior art to be a legitimate response to an unforeseeable amendment. In the present case, the filing of document D8 is therefore not justified by procedural reasons and thus late. The Board sees no reason why D8 could not have been cited during the first instance proceedings if it was relevant. Accordingly, D8 represents evidence

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which could already have been presented in the first instance proceedings and which can be held inadmissible pursuant to Article 12(4) RPBA.

The purpose of the inter partes appeal procedure is mainly to give the losing party an opportunity to challenge the decision against it and to obtain a judicial ruling on whether a first-instance decision is correct (see G 9/91 and G 10/91). The appeal proceedings are thus largely determined by the factual and legal scope of the preceding opposition proceedings. Consequently, the parties have only limited scope to amend the subject of the dispute in second-instance proceedings, and the appeal proceedings are not about bringing an entirely fresh case (see "Case Law of the Boards of Appeal of the EPO", 6th Ed. 2010, VII.E.16.2.1). In the present case, the filing of document D8 at the appeal stage represents an attempt to have the Board consider a different factual framework than the Opposition Division, contrary to the purpose of the appeal procedure.

Finally, the Board does not share the appellant's view that D8 is particularly relevant. D8 is not concerned with the dissolving of a powder but merely relates to the further dilution of a liquid concentrate (9). D8 fails to disclose the monitoring of the concentration in the recirculation circuit and stopping the recirculation when an appropriate concentration is reached. The conductivity sensor (17) is used only after the recirculation has been stopped for checking the concentration of a bolus of liquid to be extracted from the device (see column 5, lines 13 to 24). For this reason, document D8, even if taken alone or in

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combination with D7, would not have been relevant enough to be admitted into the procedure at this late stage.

Accordingly, the Board exercises its discretion under Article 114(2) EPC in combination with Article 12(4) RPBA not to admit document D8, also in consequence of the fact that D7 is not in the procedure.

- 3.4 Inventive step
- 3.4.1 Document D1 as closest prior art discloses a method for preparation of a fluid intended for medical use which method undisputedly comprises features [a] to [e] of claim 1.
- 3.4.2 From line 66 to 68 of column 7 of Dl it is clear that between the "cycling" step mentioned in the third to the last sentence of the abstract and the "circulation" step mentioned in the next sentence, the valve 82 is closed and the wand 16 empties the drum 12 of all liquid. Then, the wand 16 is disconnected from the flexible conduit 96 and the conduit is instead attached to the coupling 116 of suction pipe 112 (see lines 4 to 7 of column 8 of Dl). Accordingly, the "cycling" mentioned in the abstract is around a different circuit than the "circulation" mentioned in the subsequent sentence. The abstract of Dl neglects to mention the disconnection step since it represents a short summary of the most important steps of Dl. Although the abstract of Dl mentions a cycling step followed by a circulation step, this cannot, and must not, be taken as a teaching in Dl that no disconnection step occurs between the cycling and circulation step. On the

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contrary, the only disclosure in Dl involves such a disconnection step. Indeed, the disconnection step makes perfect sense given that the first cycling continues "until all of the chemicals in the drum have been removed". It is quite clear that Dl teaches emptying the drum 12 of chemicals in a first circuit and then performing circulation around a different circuit to mix the chemicals.

Feature [f] of claim 1 specifies recirculating water through the mixing vessel after ending supply of the water. Column 7, lines 14 to 17, and column 8, lines 13 to 16 of Dl however disclose that further water is added to the tank 10 after recirculation through drum 12.

Feature [g] of claim 1 states that monitoring takes place in the recirculation circuit. No monitoring at all takes place in the circuit involving drum 12 of D1. Neither does any monitoring take place in the circuit involving tank 10. Dl discloses only checking (once) the conductivity after the fluid has left the tank 10 (see column 8, lines 17 to 22). There is no monitoring in any recirculation circuit. The term "monitoring" implies continuous or repeated measuring. It is clear from lines 17 to 24 of column 8 of Dl that any measuring that takes place in the Dl device is after the filtering step and the filters are referenced 62, 63, 64 in Figure 1. Accordingly, the measuring performed in Dl is done at the very outlet of the device and not in the recirculation circuit.

Feature [h] of claim 1 requires stopping recirculation when the monitored concentration reaches an appropriate

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value indicating complete dissolving. In D1, recirculation through the drum 12 is stopped once all the chemicals have been removed from the drum 12, and not at a point of complete dissolution. Lines 53 to 54 of column 8 suggest that this stage is controlled using an automatic timer. Accordingly, it is quite clear that some other method is used for determining when to stop recirculation in the D1 device (such as a timer) and there is no automatic stopping of the recirculation when the monitored concentration reaches an appropriate value. Indeed, it would be impossible for the D1 device to provide this functionality because any conductivity measuring step is carried out only on the final liquid product presented to the "dispense" block of Figure 1 and not in the recirculation circuit itself.

Accordingly, the subject-matter of claim 1 is distinguished over the disclosure of D1 by features [f] to [h].

3.4.3 The technical effect achieved by the above-mentioned distinguishing features is that the claimed method can be used for salts or "powders" of different solubility without calibration, because the decision to stop recirculation is based on the monitored conductivity level, thereby automatically taking account of the possibility of varying lengths of time for complete dissolution of the powder. For the system of Dl, on the other hand, some calibration and programming would be necessary to ensure that the circulation step continues for as long as necessary to dissolve the particular salt. Each time the salt is changed, the system would need re-calibrating.

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- 3.4.4 The objective technical problem to be solved is to provide a method for the preparation of a dialysis fluid or concentrate solution that is more efficient. Although not explicitly stated in the specification of the patent in suit, this problem is derivable from its overall content for the person skilled in the art. The Board does not accept the formulation of the problem proposed by the appellant, namely to further develop the control of D1 such that it can be determined whether the powder has completely dissolved, since this formulation already implies a pointer to the solution, which is not appropriate according to established jurisprudence (cf. "Case Law of the Boards of Appeal of the EPO", 6th Ed. 2010, I.D.4.3.1).
- 3.4.5 The objective problem is solved by features [g] and [h] because fluid is only recirculated for as long as is necessary to completely dissolve the fluid. No timers are needed which can result in not enough powder dissolving (if the timers are set too short) or wasted time recirculating already dissolved fluid (if the timers are set too long).
- 3.4.6 It cannot fairly be said that the inventive solution is obvious in view of general technical knowledge. It is, of course, generally known that different salts may have different solubilities, thus requiring different amounts of time to be dissolved. This information alone, however, does not lead the skilled person towards monitoring the concentration and stopping the recirculation if the monitored concentration indicates complete dissolution as defined in features [g] and [h], instead of setting a timer as suggested in D1. It is also not obvious for the skilled person to perform the

conductivity measurement in the recirculation circuit instead of checking conductivity after the fluid has left the tank 10 of D1 when trying to avoid that fluid not yet ready for use is removed, as suggested by the appellant. Even if this were the case, it would still be necessary to monitor the concentration/conductivity over time as required in feature [g] and to stop the recirculation as defined in [h] in order to arrive at the invention.

3.4.7 Document D2 does not address the problem of efficiency. Accordingly, there is no reason for the skilled person to consider its teaching when trying to solve the above-mentioned objective problem (point 3.4.4). Figure 7.2.1.1 of D2 shows a spoonful of powder being dumped into a tank, corresponding to the mixing vessel defined in feature [a]. The drawing further shows a "Ringleitung", which could be equated to a recirculation circuit as defined in feature [c], and a conductivity sensor located in a sampling duct leading from the "Ringleitung" to a separate container. D2 merely discloses a one-off conductivity check that is carried out on a batch of withdrawn liquid. Accordingly, D2 does not disclose any monitoring as required by feature [q]. As discussed above, "checking" or "measuring" is not the same as "monitoring". The checking step disclosed in D2 is done on a withdrawn batch of fluid and so it is questionable whether it can be said that it is done in the recirculation circuit, as required by feature [g]. Finally, D2 fails to disclose any link between the checking step and any recirculation. In particular, D2 does not teach any method for determining when to stop a recirculation. Certainly, D2 does not link the checking step with any

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stopping of a recirculation. D2 is entirely silent regarding feature [h].

Figure 7.2.4 of D2 is even less relevant. It shows a dialyser which would be located downstream of the apparatus shown in Figure 7.2.1.1. In Figure 7.2.4 the fluid bypasses the dialyser if its (monitored) temperature or conductivity/concentration is not correct. This gives a hint towards monitoring the concentration, but under entirely different circumstances and for a different purpose since the fluid is thus wasted and not recirculated.

Accordingly, aside from the fact that D2 does not address the objective technical problem (point 3.4.4) and so would not have been studied by the skilled person, D2 does not teach the solution claimed in the present claims and a combination of D1 and D2 does not result in the invention as claimed.

3.4.8 The Board is satisfied that the subject-matter of claim 1 is based on an inventive step within the meaning of Article 56 EPC. The same applies to claim 9 which corresponds to claim 1 in terms of apparatus features.

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Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

The case is remitted to the department of first instance with the order to maintain the patent in amended form on the basis of the following documents:

Claims:

Nos. 1 to 19 according to the first auxiliary request received on 7 April 2009

Description:

page 2 received on 2 March 2007
pages 3 and 4 of the patent specification

Drawings:

Figures 1 to 4, 5a and 5b of the patent specification.

The Registrar: The Chairman:

D. Hampe P.L.P. Weber