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

Case Number: T 1507/22 - 3.3.05

Application Number: 14165145.5

Publication Number: 2933010

IPC: B01D63/02, B01D61/24

Language of the proceedings: EN

Title of invention:

Thermoforming of fibre bundles

Patent Proprietor:

Gambro Lundia AB

Opponent:

B. Braun Avitum AG

Headword:

Fibre bundle/Gambo Lundia

Relevant legal provisions:

EPC Art. 100(b), 100(a), 54, 56

Keyword:

Novelty - (yes)
Inventive step - (yes)
Sufficiency of disclosure - (yes)

Decisions cited:

T 1931/14

Catchword:



Beschwerdekammern

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Case Number: T 1507/22 - 3.3.05

D E C I S I O N
of Technical Board of Appeal 3.3.05
of 18 April 2024

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Decision under appeal: **Decision of the Opposition Division of the
European Patent Office posted on 5 April 2022
rejecting the opposition filed against European
patent No. 2933010 pursuant to Article 101(2)
EPC.**

Composition of the Board:

Chairman E. Bendl
Members: S. Besselmann
O. Loizou

Summary of Facts and Submissions

- I. The opponent's appeal is against the opposition division's decision to reject the opposition against European patent EP 2 933 010 B1.
- II. The following documents are of relevance here:
- | | |
|-----|--|
| D1 | JP 64-47410 A |
| D1a | Machine translation of D1 into English |
| D2 | DE 10 2010 024 976 B4 |
| D3 | US 6,872,346 B2 |
| D4 | US 4,138,460 A |
| D9 | DE 38 50 713 T2 |
| D13 | DE 603 13 818 T2 |
- III. Independent claim 1 of the patent as granted reads as follows:
- "A process for the production of a capillary dialyzer comprising a bundle (10) of hollow fiber membranes disposed within a tubular casing (15), the process comprising forming a contiguous annular zone (13, 18) on the perimeter of an end of a bundle (10) of hollow fiber membranes by shaping an end of the bundle (10) to have a circular cross-section; and compacting and melting together the fibers on the perimeter of the bundle (10) of hollow fiber membranes."*
- Claims 2-11 relate to particular embodiments.
- IV. The appellant's arguments, where relevant to the present decision, can be summarised as follows:
- The respondent's reply to the grounds of appeal did not fulfil the requirement of substantiation and should therefore be disregarded (Articles 12(3) and (5) RPBA).

Moreover, the claimed invention was insufficiently disclosed in view of the feature relating to a "contiguous annular zone", and because the term "thickness" in claim 2 was undefined.

When assessing novelty and inventive step, it should be kept in mind that the reference to a "capillary dialyser" did not provide a clear delimitation of the claimed process. The feature relating to a contiguous annular zone had to be construed broadly and encompassed embodiments in which the fibre bundle was melted together in a disc-like manner.

The subject-matter of claim 1 of the patent as granted lacked novelty in view of each of documents D1, D2, D3 and D9.

Furthermore, it lacked an inventive step in view of each of D1, D13 and D4 as the closest prior art.

- V. The patent proprietor (respondent) concurred with the impugned decision.

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

- VII. The respondent 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 I to III of 12 February 2021 as filed during the opposition proceedings.

Reasons for the Decision

Main request (patent as granted)

1. Articles 12(3) and (5) RPBA
 - 1.1 According to the appellant, the respondent's reply to the appeal should not be taken into consideration because it merely referred to the impugned decision and therefore did not fulfil the requirements of substantiation pursuant to Article 12(3) RPBA.
 - 1.2 In their reply to the appeal, the respondent merely indicated that they were in complete agreement with the decision of the opposition division rejecting the opposition and the reasons detailed therein (second page of the reply to the appeal). It is therefore correct that the respondent's submission was very brief. However, the appeal proceedings are necessarily based on the impugned decision (Article 12(1) RPBA). Consequently, no part of the respondent's submission in relation to the main request could possibly be disregarded.
 - 1.3 There is no scope for Articles 12(3) and (5) RPBA to be applied.
2. Sufficiency of disclosure (Article 100(b) EPC)
 - 2.1 According to the appellant, the claimed invention was insufficiently disclosed because the skilled person would not know how to carry out the invention in view of the term "contiguous annular zone".

2.2 However, this term is not used in isolation; claim 1 sets out that the process comprises forming a contiguous annular zone on the perimeter of an end of a bundle of hollow fibre membranes by shaping an end of the bundle so as to have a circular cross-section, and compacting and melting together the fibres on the perimeter of the bundle of hollow fibre membranes.

A detailed description of one way of carrying out this process is provided in paragraphs [0009] to [0020], and no reason is apparent as to why the skilled person would not be able to carry it out.

The question of how the skilled person would construe the term objected to by the appellant would in fact be a matter of clarity (Article 84 EPC), as per the view of the opposition division.

2.3 The appellant also raised an objection against the subject-matter of claim 2. According to the impugned decision, the question of how the "thickness" was defined was a matter of clarity (point 11.3 of the impugned decision). This finding is correct, and the appellant provided no counter-argument in their statement of grounds of appeal.

2.4 The objections regarding a lack of sufficiency of disclosure are not convincing and therefore dismissed.

3. Novelty (Article 100(a) EPC and Article 54 EPC)

3.1 *Document D1*

- 3.1.1 The disclosure of D1 can only be assessed on the basis of the machine translation provided by the appellant as D1a.
- 3.1.2 The subject-matter of claim 1 is novel over D1, at least because D1 does not directly and unambiguously disclose the production of a capillary dialyser, nor a step of forming a contiguous annular zone within the meaning of the claim.
- 3.1.3 Even though claim 1 does not recite all of the features and process steps that would be necessary to produce a capillary dialyser, the claim is explicitly limited to the production of a capillary dialyser. There is no feature in the claim that would be inconsistent with this. The feature "for the production of a capillary dialyser" thus represents a technical limitation of the method, which must be applied in that manner (see Case Law of the Boards of Appeal of the EPO, 10th edn., 2022, I.C.5.2.5, in particular with reference to T 1931/14). Steps which are essential for producing a capillary dialyser consequently have to be considered to be implicit in the claim. On the contrary, the production of a bundle of hollow fibre membranes disposed within a tubular casing that would be unsuitable for use as a capillary dialyser is not encompassed by the claim.
- 3.1.4 D1 (always referring to the machine translation thereof, D1a) generally relates to a filter membrane, a gas separation membrane, or a reverse osmosis membrane (third page, first paragraph). D1 thus indicates a variety of separation tasks with different physical requirements, as is clear from comparing, for example, gas separation with the removal of fine particles from solutions. A filter membrane for removing fine

particles and colloidal substances from chemical solutions is specifically mentioned (third page, second and third paragraphs), and the filter in Figure 7 is provided for this purpose (the wording "For this reason").

D1 does not specifically mention dialysis, and there is no basis to assume that any arbitrary hollow fibre membrane would be suitable for this specific application. This is not a question of the biocompatibility of the hollow fibre material alone, but also of that of other components and of the physical properties of the membrane. In particular, there is no proof that the filter shown in Figure 7 would be suitable for use as a dialyser; moreover, this figure illustrates the prior art, see page 11 of D1a.

- 3.1.5 The appellant did not contest the opposition division's finding that D1 did not explicitly disclose that a contiguous annular zone on the perimeter of an end of a bundle of hollow fibre membranes was formed (page 7 of the impugned decision, starting at line 13). However, the appellant was of the opinion that this feature was nevertheless anticipated.

Specifically, the appellant held that the feature relating to forming a contiguous annular zone needed to be construed broadly and did not exclude that the remaining fibres of the circular cross section of the end of the bundle, i.e. the fibres in the interior of the contiguous annular zone, were also melted together.

- 3.1.6 However, if all of the fibres at the end of the bundle, over the entire cross section, were melted together in a disc-like manner, it would be impossible to identify a contiguous annular zone on the perimeter of the end

of the bundle, because there would be no structural difference between the annular zone and the remainder. Moreover, if the contiguous annular zone were to be constituted by all of the fibres, there would have been no need to specify that the zone is formed on the perimeter of the end of the bundle. Hence, the claim cannot be reasonably interpreted such that all of the fibres are melted together at the end of the bundle in the same way, and that the annular zone is only conceptually present.

- 3.1.7 The appellant also argued that it was technically irrelevant which portion of the end of the bundle was melted together because the end would eventually be cut away. However, this argument concerns the resulting product and is irrelevant to the question of the novelty of process claim 1. The claim relates to a process which, as an essential feature, involves the indicated formation of the contiguous annular zone.
- 3.1.8 The appellant additionally argued that the inevitable consequence of using a band heater 9 in D1 was that a contiguous annular zone within the meaning of the claim resulted. Using the band heater alone was disclosed in D1, which stated that "For example, in the state shown in Fig. 1, the end portion 1a of the hollow fibre membrane may be heated by the band heater 9 alone or by the heating plate 4 and the band heater 2" (page 10, fifth paragraph).
- 3.1.9 This argument is not convincing either. To anticipate the claimed feature, a contiguous annular zone must be the identifiable result of a process step. In this case, the feature is not anticipated if a contiguous annular zone supposedly forms as a transient state in the course of a heating step, as is the case when a

band heater is used. This is all the more so as there is no indication that the purpose of using a band heater would be different to that of using other heating means, for instance heating plate 4, which is explicitly associated with heating the end portions of the hollow fibre membranes *uniformly* in the radial direction (page 8, last paragraph).

The indication in D1 that "even if the temperature distribution in the radial direction becomes somewhat uneven due to the heating from the outer periphery by the band heater 9, the phenomenon such as the collapse of the hollow fibre membrane can be effectively prevented" (page 9, fourth paragraph) merely discusses the possible risk of using a band heater 9; it cannot be understood as a direct and unambiguous disclosure of a radial melting profile resulting in a contiguous annular zone.

3.1.10 The objection of a lack of novelty in view of D1 is therefore not convincing.

3.2 *Document D2*

3.2.1 The appellant was of the opinion that the process depicted in Figure 1 of D2 involved forming a contiguous annular zone on the perimeter of an end of a bundle of hollow fibre membranes by melting together the fibres on the perimeter of the bundle. Specifically, they argued that the infrared radiator 8 was directed at the end of the bundle having the clamp (Figure 3), and that therefore the fibres on the perimeter inevitably melted according to the profile depicted in the statement of grounds of appeal (page 21).

3.2.2 These arguments are not convincing. The purpose of the process of D2 is to heat and seal the entire end surface ([0009]). The infrared radiation is thus directed at the entire end surface. The appellant's assertion that there was indirect radial heating via the clamp, allegedly resulting in the depicted temperature profile (page 21 of the statement of grounds of appeal), is not supported by any disclosure in D2. Instead, the protruding surface of the clamp is explicitly associated with improved heat distribution (paragraph [0013]). There is therefore no direct and unambiguous disclosure of forming a contiguous annular zone on the perimeter of the bundle.

3.2.3 The objection of a lack of novelty in view of D2 is therefore not convincing.

3.3 *Document D3*

3.3.1 In the method of D3, a distance between the heat source and the bundle is regulated to maintain a (variable or constant) predefined non-zero separation distance while the tips of the bundle melt due to heating, to seal the ends of the filters (column 3, lines 1-7; claim 1) in preparation for potting. It is thus clear that the fibre tips over the entire end face of the bundle melt in a disc-like manner. Hence, no contiguous annular zone is formed.

3.3.2 The appellant's objection in view of D3 is based, *inter alia*, on their interpretation of claim 1 according to which the contiguous annular zone did not exclude that the remaining fibres of the circular cross section of the end of the bundle, i.e. the fibres in the interior of the contiguous annular zone, were melted together in

the same way. This interpretation cannot be accepted, as already indicated (see point 3.1.6 above).

The appellant specifically cited the embodiment in D3 according to which a heater 800 having annular rapid heating filaments 810 was used (Figure 13). However, the appellant's assertion as to the resulting temperature profile is speculative. There is no indication of a different axial melting depth in the centre of the bundle compared with the perimeter in D3, nor would such a difference be desirable in view of the purpose of the melting step in D3, namely to seal the ends of the filters. Instead, a defined boundary between melted and unmelted fibre is desired (column 4, penultimate paragraph).

3.3.3 The objection of a lack of novelty in view of D3 is therefore not convincing either.

3.4 *Document D9*

3.4.1 According to the impugned decision, D9 did not disclose the production of a capillary dialyser. It also failed to disclose a step of compacting the fibres and of forming a contiguous annular zone on the perimeter of an end of the bundle (page 9, point 6.3 of the impugned decision).

3.4.2 The appellant was of the opinion that the hollow fibre filter element known from D9 was suitable for use as a dialyser because polyethylene was a preferred material for making the hollow fibres (D9, page 8, first full paragraph), and was biocompatible.

However, D9 is silent as to this use and the mere reference to polyethylene as the material of the hollow

fibres does not prove that the filter element is suitable for use as a dialyser (see also the comments regarding D1, point 3.1.4 above).

3.4.3 According to the appellant, the disclosure in D9 that the fibres were melted together on their perimeters anticipated the feature of melting together the fibres on the perimeter of an end of the bundle. However, D9 states that the ends of the membranes are fused together on their respective perimetrical areas, forming a uniform end block (claim 1; see also the examples). The reference to the perimetrical areas thus relates to the individual membranes (fibres), not to the bundle as a whole. The end of the bundle, by contrast, is described as a uniform end block. A uniform end block does not constitute a contiguous annular zone within the meaning of claim 1 (see also the comments regarding claim construction, point 3.1.6 above).

3.4.4 The objection of a lack of novelty in view of D9 is therefore not convincing either.

3.5 For these reasons, novelty is given, in line with the opposition division's findings.

4. Inventive step (Article 100(a) EPC and Article 56 EPC)

4.1 The patent in suit relates to the production of capillary dialysers involving the thermoforming of bundles of hollow fibre membranes (paragraph [0001]).

4.2 According to the appellant, any one of D1, D13 and D4 could be regarded as the closest prior art. D1 was additionally cited as a secondary document to be

combined with D13 or D4. Alternatively, D9 could be combined with D4 but is said to be similar to D1.

The appellant's arguments thus largely rely on D1.

4.3 *Starting from document D1*

4.3.1 D1 relates to a hollow fibre membrane bundle and is therefore a suitable starting point for assessing inventive step.

4.3.2 As follows from the considerations regarding novelty, D1 does not disclose the production of a capillary dialyser, nor a step of forming a contiguous annular zone within the meaning of claim 1 (point 3.1.2 above). Since the two distinguishing features are not necessarily linked, and in the absence of any synergetic effect, separate partial technical problems may be formulated. The discussion of inventive step focussed on only one of these features, namely the step of forming a contiguous annular zone.

4.3.3 The technical problem associated with forming the contiguous annular zone is to provide an alternative way to form the end of the bundle.

4.3.4 Thermoforming the ends of the bundle, as described in claim 1, simplifies the transfer of the fibre bundle into the tubular casing (paragraph [0021]) but does not serve to seal the bundle. The desired effect in D1, by contrast, is to fuse the outer periphery of the end of *each* hollow fibre membrane to each other, to fuse the end of the bundle in a honeycomb shape *uniformly* and with good sealability without using an adhesive (page 10, Effect of the Invention). This desired effect of D1 would not be obtained with a radial temperature

gradient such that a contiguous annular zone was formed by melting together the fibres on the perimeter of the bundle.

4.3.5 The board agrees with the appellant that the membrane bundle known from D1, with each of the hollow fibre membranes fused to each other, i.e. in a disc-like manner across the whole cross-section, inherently provides the additional effect of simplifying the transfer of the fibre bundle. Moreover, even though this is not specified in the claim, the process taught in the patent in suit at some stage necessarily involves melting together all of the hollow fibre membranes, either directly or using a potting agent, for the formation of end walls within the tubular casing to provide a functional dialyser, as is clear from paragraph [0023] of the patent in suit.

4.3.6 The appellant was of the view that there was consequently no functional difference between the claimed process and the prior art. In their opinion, it was obvious to interrupt the fusing step in D1 before the entire face of the bundle was fused together, such that an annular zone was obtained, and to then continue it again. According to the appellant, nothing inventive could be seen in splitting a known step into two sub-steps, namely a first sub-step of only fusing together the perimeter of the bundle and another sub-step to finalise the uniform fusing together. Such a method with two sub-steps fell within the scope of claim 1 of the patent in suit.

The appellant submitted that the effect of facilitating the transfer of the bundle was not only inherently obtained in D1 but was also readily recognised by the skilled person.

4.3.7 The board does not concur with the appellant's conclusion. D1 does not discuss facilitating the transfer of the bundle and it cannot be derived from that document that there could be any interest in fusing (only) an annular zone, even as an intermediate product.

The teaching of D1 is clearly towards heating and fusing uniformly in a disc-like manner, namely to fuse the outer periphery of the end of *each* hollow fibre membrane to each other, to fuse the end of the bundle in a honeycomb shape *uniformly* and with good sealability without using an adhesive (page 10, Effect of the Invention). It is not the case that this fusing step in D1 would necessarily pass through the formation of an annular zone on the perimeter of the bundle as an intermediate state. As outlined with regard to novelty (point 3.1.9), D1 discloses various heating means, for instance a heating plate 4 (Figure 1), which is associated with heating the bundle *uniformly* in the radial direction (page 8, last paragraph). It cannot be used for fusing an annular zone within the meaning of the claim. There is no indication that the purpose of using a band heater would be different to that of using other heating means, for instance heating plate 4. Even though a band heater may provide a radial temperature gradient, this is not seen as beneficial in D1, as can be derived from the discussion of an uneven temperature distribution (page 9, fourth paragraph).

The skilled person carrying out the process of D1 would therefore steer the heating process as far as possible towards a uniform temperature profile, and in particular a uniform melting profile, even when using a band heater. This teaches away from the process of

claim 1. Indeed, conducting the heating process in such a manner that a contiguous annular zone would be obtained as an intermediate product, interrupting and then continuing the heating process would not contribute to a uniform heating profile, but rather the opposite.

4.3.8 In light of the above, the skilled person starting from D1 would not have arrived in an obvious manner at a process according to claim 1.

4.3.9 Combining D1 with D4 or D13 would not lead to a different result, as the relevant features distinguishing the process according to claim 1 from the disclosure of D1, i.e. the the step of forming a contiguous annular zone under consideration here, cannot be derived from D4 or D13 either.

4.4 *Alternative starting points*

4.4.1 According to an alternative approach, the appellant started from D13. It was not contested that D13 did not disclose forming a contiguous annular zone on the perimeter of an end of the bundle. According to the appellant, this feature was rendered obvious by D1.

This argumentation is not convincing. For the reasons indicated above (points 3.1.6 and 4.3.7), D1 neither discloses nor renders obvious forming a contiguous annular zone on the perimeter of an end of the bundle.

4.4.2 In a further approach, the appellant started from D4. However, D4 does not mention any contiguous annular zone within the meaning of claim 1, nor any step of melting together the fibres on the perimeter of the bundle. Instead, D4 discloses positioning a tow of

fibres in a mould, flowing a polymeric composition through the interstices between the fibres to fill the interstices between the fibres and the mould, and causing the polymeric composition to solidify adjacent to the axial ends of the mould (claim 1 of D4).

Even if the skilled person were to turn to D1 to find an alternative to the use of a polymeric composition as an adhesive, they would not arrive at a method which involves forming a contiguous annular zone on the perimeter of an end of the bundle by melting together the fibres on the perimeter of the bundle, because there is no such teaching in D1, as already indicated above (point 4.3.7).

The same conclusion applies if the skilled person were to turn to D9 as the secondary document. According to the appellant, D9 is similar to D1. D9 neither discloses nor renders obvious forming a contiguous annular zone on the perimeter of an end of the bundle; instead it discloses forming a uniform end block (see point 3.4.3 above).

- 4.5 The subject-matter of claim 1 consequently involves an inventive step, in line with the opposition division's findings.
- 4.6 Claims 2-11 directly or indirectly depend on claim 1 and thus involve an inventive step for the same reason.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:



C. Vodz

E. Bendl

Decision electronically authenticated