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Datasheet for the decision of 13 March 2025

Case Number: T 2490/22 - 3.2.02

Application Number: 12008235.9

Publication Number: 2604299

IPC: A61M1/00, A61M27/00

Language of the proceedings: EN

Title of invention:
Device for wound therapy

Patent Proprietor:
Smith & Nephew, Inc.

Opponents:
KCI Manufacturing Unlimited Company
Pajaro Limited

Headword:

Relevant legal provisions:
EPC Art. 54, 56, 76(1), 104(1), 123(2)
RPBA 2020 Art. 12(4), 16(1)

Keyword:

Amendments - added subject-matter (no)
Novelty - (yes)
Inventive step - (yes)
Amendment to case - amendment admitted (no)
Apportionment of costs - (no)

Decisions cited:

Catchword:

Europäisches Patentamt
European Patent Office
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Beschwerdekammern

Boards of Appeal

Chambres de recours

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Case Number: T 2490/22 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 13 March 2025

Appellant: (Patent Proprietor)	Smith & Nephew, Inc. 1450 Brooks Road, Memphis, TN 38116 (US)
Representative:	HGF HGF Limited 1 City Walk Leeds LS11 9DX (GB)
Appellant: (Opponent 2)	Pajaro Limited 12 New Fetter Lane London EC4A 1JP (GB)
Representative:	Bird & Bird LLP Maximiliansplatz 22 80333 München (DE)
Party as of right: (Opponent 1)	KCI Manufacturing Unlimited Company IDA Business & Technology Park Dublin Road Athlone, Co. Westmeath (IE)
Representative:	Simmons & Simmons City Point One Ropemaker Street London EC2Y 9SS (GB)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 28 September 2022 concerning the maintenance of European Patent No. 2604299 in amended form**

Composition of the Board:

Chairman	M. Alvazzi Delfrate
Members:	D. Ceccarelli
	C. Schmidt

Summary of Facts and Submissions

I. The patent proprietor and opponent 2 appealed against the Opposition Division's decision that, account being taken of the amendments made by the patent proprietor during the opposition proceedings in accordance with auxiliary request 2 then on file, the patent and the invention to which it related met the requirements of the EPC.

II. The Board summoned the parties to oral proceedings and provided its preliminary opinion.

III. By letter dated 22 January 2025, the appellant/ opponent 2 ("opponent 2") announced that it would not attend the oral proceedings.

IV. Oral proceedings took place on 13 March 2025 in the absence of opponent 2, which was treated as relying only on its written case, in accordance with Rule 115(2) EPC and Article 15(3) RPBA.

The appellant/patent proprietor ("the proprietor") requested that the decision under appeal be set aside and that the patent be maintained as granted ("main request") or on the basis of the first or the second auxiliary request, both filed with the letter dated 27 January 2023.

The respondent/opponent 1 ("opponent 1") requested that the proprietor's appeal be dismissed.

Opponent 2 had requested in writing that the decision under appeal be set aside and that the patent be

revoked.

V. The following documents are mentioned in this decision:

D1: US 2005/0222544 A1
D2: DE 20 2004 017 052 U1
D4: WO 2005/123170 A1
D11: Judgment of the Federal Patent Court of Germany, 4 Ni 12/15 (EP)
D12: WO 2007/030598 A2
D14: US 2008/0119802 A1
D15: DE 20 2004 017 465 U1
D16: DE 20 2005 019 670 U1
D17: FR 1.163.907
D24: US 2007/0185426 A1
D25: WO 94/20041 A1
D26: "Dubbel - Taschenbuch für den Maschinenbau", KH Grote and J Feldhusen, Springer, 21st edition, pages F14-F15, 2005
D27: "Pahl/Beitz Konstruktionslehre- Methoden und Anwendung erfolgreicher Produktentwicklung", J Feldhusen and KH Grote, Springer, 8th edition, pages 553-561, 2013

VI. **Claims 1, 6, 7, 15 and 16 of the main request** read as follows:

"1. A wound therapy device configured to provide negative pressure therapy to a wound, comprising:

a housing (20; 120; 220; 420; 520; 820) configured to cover at least a portion of a wound;
a liquid-retention chamber (40; 140; 240; 440; 540; 640, 640'; 840) positioned inside of the housing;

a liquid absorbing structure (776) within the liquid-retention chamber;
a vacuum connection (30; 32; 130, 132; 232; 432) for coupling to a vacuum source (134; 234; 434; 534; 634; 634'), the vacuum connection in gaseous communication with the liquid retention chamber;
a liquid barrier (36; 136; 236; 436; 636; 636') configured to prevent liquid travel from the liquid absorbing structure into the vacuum connection while allowing gas flow,
characterized in that
the liquid barrier is positioned inside the housing,
and in that the liquid absorbing structure comprises super-absorbent polymers that form gels to assist in retaining the liquid drawn into the liquid-retention chamber."

"6. The wound therapy device of Claim 1, wherein the liquid absorbing structure (776) comprises a porous structure that permits the flow of gas to allow the vacuum to be applied to the wound while absorbing and retaining liquid drawn out of the wound."

"7. The wound therapy device of Claim 6, wherein the porous structure is chosen from: a sponge, packing material, a gelling agent, a super-absorbent polymer material and combinations thereof."

"15. The wound therapy device of Claim 2, wherein the liquid barrier is distinct from the seal."

"16. The wound therapy device of any one of Claims 1-15, wherein the liquid barrier prevents travel of liquid from the liquid-retention chamber into a

vacuum chamber (24)."

Claims 2 to 5, 8 to 14 and 17 to 23 are further dependent claims.

VII. The arguments of opponent 1, where relevant to this decision, can be summarised as follows.

Extension of subject-matter

There was no basis in the application as filed or in the parent application as filed for a liquid barrier inside a housing but without a vacuum chamber inside the housing.

Paragraphs [0024] and [0028] of the application and the parent application as filed, which related to the embodiment of Figure 2, disclosed a liquid barrier inside a housing, but only in a position and with a function in which it separated a liquid-retention chamber from a vacuum chamber, also both inside the housing.

The embodiment of Figure 3 did not provide a basis for claim 1 either. Paragraph [0037] described a dressing with a liquid-retention chamber and a vacuum chamber. There was no suggestion of a device without that vacuum chamber. The vacuum chamber could act as a droplet gap and hence removed the need for a further liquid barrier. However, this disclosure was specific to a vacuum chamber acting as a droplet gap and could only provide a basis for a vacuum chamber configured as a droplet gap. Claim 1 was much broader and included any type of liquid barrier.

Paragraph [38] of the application and the parent

application as filed described a further embodiment in which a hydrophobic membrane was positioned around a droplet-gap structure (which was a vacuum chamber). In this embodiment, the vacuum chamber was still present together with a specific form of liquid barrier. Nor could this embodiment provide a basis for the generality of claim 1 of the main request.

In conclusion, the application and the parent application as filed disclosed three discrete embodiments which could not be generalised to exclude the vacuum chamber since such a chamber was present in all embodiments.

The vacuum chamber was functionally and structurally linked to the position of the liquid barrier because the barrier separated the two chambers and prevented liquid flow between them as described in paragraph [0028]. Without a vacuum chamber, the liquid barrier would lie on the internal surface of the housing. This would mean that the only route for negative pressure into the liquid collection chamber would be through the small area of the liquid barrier directly underneath the port and directly into the absorbent material. Exudate and other material from the wound would be drawn to that area and would block the passage of gas, thus preventing the application of negative pressure to the wound. The vacuum chamber was required to distribute the reduced pressure across the area of the liquid barrier, thus preventing movement of exudate to one location and the consequential blocking of the gas flow required to deliver reduced pressure. The vacuum chamber thus worked together with the liquid barrier to ensure that reduced pressure could reach the wound being treated. The features were thus interlinked, and the vacuum chamber could not be omitted.

Claim 16 of the main request also included added subject-matter. The only disclosure of a vacuum chamber in the parent application as filed was a vacuum chamber within the housing, with a certain function. According to claim 16, however, a vacuum chamber could be located anywhere in the system, such as outside of the housing, provided that the liquid barrier prevented the travel of liquid to the chamber. In the parent application as filed, there was no disclosure of a vacuum chamber outside of the housing. The lumen of a tube could not be considered a vacuum chamber according to the claims of the main request.

Inventive step

The subject-matter of claim 1 of the main request was not inventive when starting from D1. D1 disclosed a wound therapy device with a liquid barrier positioned inside a housing in paragraph [0064] as this paragraph disclosed a hydrophobic filter positioned within a reduced pressure supply port that formed part of the housing. If it was concluded that D1 did not disclose that the liquid barrier was inside the housing, this distinguishing feature would be trivial. The liquid barrier would perform precisely the same function whether it was positioned in an outlet of the housing in the form of a pressure supply port or just within the housing itself, for example, across the mouth of the outlet. The distinguishing feature would not involve a technical difference or a technical effect as in both positions the barrier would prevent the passage of liquid. Hence, it would have been an obvious, arbitrary choice for the person skilled in the art to position the liquid barrier inside the housing for the liquid barrier to perform its function of retaining

liquid inside the collection chamber.

Whether a wound therapy device according to claim 1 of the main request would ensure that the liquid was collected exclusively within the housing, which could then safely be disposed of, was irrelevant. This effect was provided also by D1 as the liquid barrier was in the pressure supply port, which would be disposed of together with the housing part.

The proprietor's argument that the person skilled in the art would not have been motivated to change the position of the liquid barrier in the device of D1 because in use the housing of D1 was intended to collapse and the liquid barrier would be brought into contact with the wound was not convincing either. This was not necessarily the case with the wound therapy device according to D1.

In conclusion, the subject-matter of claim 1 of the main request was not inventive when starting from D1.

VIII. The arguments of opponent 2, where relevant to this decision, can be summarised as follows.

Extension of subject-matter

The parent application as filed disclosed the feature of a housing configured to cover at least a portion of a wound with a liquid-retention chamber and a liquid absorbing structure only as a "rigid or semi-rigid housing" or supported by structural supports. The claimed general definition of the housing comprised added subject-matter.

Claim 1 of the parent application as filed specified a

vacuum connection separated from the liquid-retention chamber by a liquid barrier. This information was missing from claim 1 of the main request because it was not implied by the feature that the liquid barrier prevented the travel of liquid while allowing gas flow from the liquid-retention chamber to the vacuum connection.

A liquid barrier preventing the travel of liquid while allowing gas flow from the liquid-retention chamber to the vacuum connection had only been disclosed in the context of the embodiments of Figures 1 and 2 of the parent application as filed. The embodiment of Figure 3 did not comprise a liquid absorbing structure in the liquid-retention chamber, hence it could not form a basis for the claimed subject-matter. In the parent application as filed, the liquid barrier as claimed had been disclosed in addition to a vacuum chamber, a rigid or semi-rigid housing, the subdivision of the internal space of the housing into a vacuum chamber, and the liquid-retention chamber separated by the liquid barrier and with the liquid barrier in the form of a porous hydrophobic film. However, all these additional features had been omitted from claim 1 of the main request, which, for this reason too, included added subject-matter.

The subject-matter of claims 6 and 7 of the main request extended beyond the content of the parent application as filed too. The expression "porous structure" in these claims defined a property of the liquid absorbing structure. However, according to the parent application as filed, it was the liquid-retention chamber which comprised a porous structure.

Claim 15 of the main request defined the liquid barrier

as being distinct from the seal. There was no verbatim disclosure of this feature. The proprietor had derived the feature of claim 15 from the figures, but this was not permitted without any indication in the figures.

The subject-matter of claim 16 of the main request extended beyond the content of the parent application as filed. Claim 16 defined the liquid barrier preventing the travel of liquid from the liquid-retention chamber into a vacuum chamber. The claim left open the position of the vacuum chamber, which could be outside the housing. In contrast, paragraph [24] of the parent application as filed, concerned with the embodiment shown in Figure 2, disclosed that an internal space of the housing was subdivided into a vacuum chamber and the liquid-retention chamber by the liquid barrier. Moreover, paragraph [28] of the parent application as filed disclosed the transmission of negative pressure through a vacuum connection. The position of the liquid barrier, the subdivision of the internal space and the transmission of negative pressure through the vacuum connection were missing from claim 16 which, for this reason, included added subject-matter, as also considered by the Opposition Division in the impugned decision.

Novelty

D2 disclosed a wound therapy device comprising all the features of claim 1 of the main request. Figures 1a to 1c illustrated an embodiment with a wound covering member 4 sealing a volume 10 above a wound. An absorbing body 2 was in the volume 10, between the wound and wound covering member 4. Volume 10 was a liquid-retention chamber. The absorbing body sucked and kept wound exudate inside it. The absorbing body was

therefore a liquid barrier as claimed. Moreover, in view of common general knowledge as evidenced by D26 and D27, a single entity fulfilling both the functions of a liquid absorbing structure and a liquid barrier would still anticipate the liquid absorbing structure and the liquid barrier as defined in claim 1 of the main request. The liquid absorbing structure and liquid barrier were not limited structurally in the claim. D26 and D27 explained that a single product could fulfil two or more functions.

D4 also disclosed a wound therapy device comprising all the features of claim 1 of the main request. The embodiment illustrated in Figure 3 comprised a housing in the form of a cover sheet 11. The space under cover sheet 11 was a liquid-retention chamber including a sponge layer 14, a silver impregnated charcoal cloth 15, a water-absorbent layer 16 and a water-permeable, size exclusion membrane separating layers 15 and 16 (page 20, lines 5 to 8 of D4), which very much resembled the embodiment of Figure 11 of the patent. Water-absorbent layer 16, possibly together with the water-permeable, size exclusion membrane, was a liquid barrier within the meaning of claim 1 of the main request. This was also in accordance with the findings of the German Federal Patent Court in a similar case dealt with in D11, as explained on pages 25 and 26 of D11.

The subject-matter of claim 1 of the main request was not novel over each of D12, D14, D15, D16 and D24. These documents were not held inadmissible by the Opposition Division. In light of its unjustified narrow claim interpretation, the Opposition Division had chosen not to assess the patentability of the claims in view of these prior-art documents. D12, D14 to D16 and

D24 should be admitted into the appeal proceedings.

Inventive step

The subject-matter of claim 1 of the main request lacked at least inventive step when starting from D1. The device illustrated in Figure 6 comprised a conical housing delimiting a collection chamber and vacuum supply port 596 in which there was a hydrophobic filter serving as a liquid barrier (claim 55 and paragraph [0064] of D1). The supply port was part of the housing as paragraph [0064] taught that the port 596 was positioned at the apex of the collection chamber. Moreover, the person skilled in the art understood that the collection chamber and the port were a single piece as manufacturing separate elements and attaching them together would have been less convenient. Under the assumption that D1 did not disclose a liquid barrier positioned inside the housing, this distinguishing feature would help to improve the reliability and durability of the wound therapy device. However, D1 by itself, as derivable from paragraph [0007], motivated the person skilled in the art to improve the reliability and durability of the wound therapy device. Manufacturing collection chamber 590 and reduced pressure supply port 596 as a single piece would avoid a costly separate mould for the reduced pressure supply port. This would result in a wound therapy device which avoided leaks and improved the mechanical stability of the device. The device would also be more reliable and durable.

The subject-matter of claim 1 of the main request lacked at least inventive step also when starting from D17, which disclosed a wound therapy device configured to provide negative pressure therapy to a wound. The

device comprised a housing containing a piece of cotton (3, Figure 1) as a liquid absorbing structure arranged within a liquid-retention chamber. The piece of cotton was also a liquid barrier according to claim 1 of the main request. Under the assumption that D17 did not disclose a liquid barrier as claimed, the technical effect of this distinguishing feature would be to improve the device of D17 for extended negative pressure therapy. Claim 3 of D17 encouraged the person skilled in the art to think of extended negative pressure wound therapy. The person skilled in the art would have replaced the piece of cotton of D17 with super-absorbent polymers, such as those disclosed in D1, D2 and other documents of the prior art, thus arriving at the identified distinguishing feature in an obvious way. Alternatively, the person skilled in the art would have adopted the absorbent body disclosed in D2 also for D17 to extend the period of negative pressure wound therapy. The absorbent body of D2 had to be positioned between the wound and the piece of cotton to use the superior ability of the absorbent body comprising a super-absorbent polymer to absorb large amounts of liquid. The person skilled in the art would have thus arrived at the identified distinguishing feature in an obvious way.

The subject-matter of claim 1 of the main request was not inventive also when starting from D25. D25 had been filed because of the Opposition Division's narrow claim interpretation provided in its preliminary opinion. Moreover, D25 was *prima facie* relevant, and the Opposition Division had not decided on the admittance of this document. D25 should be admitted into the appeal proceedings.

Proprietor's request for apportionment of costs

The proprietor's request for apportionment of costs against opponent 2 should be refused. Filing new evidence or presenting new arguments was a legitimate way of defending an opponent's interests.

IX. The proprietor's arguments, where relevant to this decision, can be summarised as follows.

Extension of subject-matter

Some of opponent 2's objections of added subject-matter had been raised late and should not be admitted into the appeal proceedings.

A basis for the definition of the housing in claim 1 of the patent as granted, without specifying that the housing was rigid or semi-rigid or supported by structural supports, was provided by claim 1 of the parent application as filed. Moreover, paragraph [21] of the parent application as filed discussed the housing as generally defining an internal space.

The feature that the liquid barrier prevented the travel of liquid while allowing gas flow from the liquid absorbing structure into the vacuum connection in claim 1 of the main request included the information of claim 1 of the parent application as filed that the vacuum connection was separated from the liquid-retention chamber by a liquid barrier. Since the liquid barrier had to prevent the travel of liquid from the liquid absorbing structure to the vacuum connection while allowing gas flow, it had to be between (and thus separate) the liquid-retention chamber and the vacuum connection.

The embodiments of Figures 2, 3, 4, 5, 6, 7, 9a, 9b and 11 and paragraphs [24], [28], [37], [40], [45], [50], and [59] of the parent application as filed provided a basis for a liquid barrier positioned inside a housing as defined in claim 1 of the main request. According to the parent application as filed, there was no structural or functional link between the liquid barrier and a vacuum chamber that would necessitate the requirement of a subdivision of the internal space of the housing into two chambers. The function of the liquid barrier was to prevent liquid travel from the liquid-retention chamber into the vacuum connection while allowing gas to flow as defined in claim 1 of the main request. This functional requirement was disclosed in paragraph [28] of the parent application as filed and could be met irrespective of whether a vacuum chamber was present within the internal space of the housing or not. The embodiment of Figure 3, which was analogous to the embodiment of Figures 1 and 2 in other respects (paragraph [38] of the application as filed), comprised a housing including a liquid-retention chamber and a vacuum passage with a port to receive an external vacuum source. Additionally, paragraph [37] of the parent application as filed disclosed that the device included a vacuum chamber acting as a liquid barrier in the form of a droplet gap. The liquid barrier was immediately proximate to the vacuum connection and did not subdivide the housing into a liquid-retention chamber and a vacuum chamber. Hence, the embodiment of Figure 3 provided a direct and unambiguous basis for the feature of the liquid barrier positioned inside the housing as defined in claim 1 of the main request. A porous hydrophobic film as a liquid barrier was not inextricably linked with the ability of the liquid barrier to allow gas flow. Paragraph [28] of the parent application as filed discusses that "*other*

technologies that allow gas flow but prevent liquid flow may also be used as suitable liquid barriers". A rigid or semi-rigid housing was not inextricably linked to the claimed liquid barrier in view of claim 1 of the parent application as filed.

The features of the porous structure as defined in claims 6 and 7 of the main request were based on claim 12 and paragraph [29] of the parent application as filed.

Paragraph [5] and Figures 2, 3, 6 and 7 of the parent application as filed disclosed the liquid barrier and the seal as being separate elements, as defined in claim 15 of the main request.

Concerning the feature of claim 16 of the main request according to which the liquid barrier prevented the travel of liquid from the liquid-retention chamber into a vacuum chamber, a vacuum chamber was disclosed in the parent application as filed, for example, in the embodiment of Figure 2. The position of the vacuum chamber was not inextricably linked with the function of the liquid barrier. Moreover, the definition of the vacuum chamber in claim 16 was broad and could refer to any element downstream of the liquid barrier. The transmission of negative pressure through the vacuum connection was inherently part of the liquid barrier feature as defined in claim 1 of the main request.

Novelty

The subject-matter of claim 1 of the main request was novel over the cited documents.

D2 did not disclose a liquid absorbing structure

together with a liquid barrier configured to prevent liquid travel from the liquid absorbing structure to the vacuum connection while allowing gas flow. The liquid absorbing structure and the liquid barrier had to be distinct and separate entities. D26 and D27 had been filed late, had not been admitted by the Opposition Division and should not be admitted into the appeal proceedings.

D4 did not disclose a liquid-retention chamber together with a liquid barrier configured to prevent liquid travel from the liquid-retention chamber to the vacuum connection while allowing gas flow. Water-absorbent layer 16 could not be, at the same time, the liquid-retention chamber and the liquid barrier as defined in claim 1 of the main request. D11 had no relevance to the current proceedings because it concerned a patent with a different claim.

D12, D14, D15, D16 and D24 had been filed late and were not admitted by the Opposition Division, which indicated in its written opinion that the admittance of these documents was to be refused. Moreover, these documents, on a *prima facie* basis, were not more relevant that the other documents in the proceeding. The Board should not admit D12, D14, D15, D16 and D24 into the appeal proceedings.

Inventive step

The objection of lack of inventive step of opponent 1 had been raised late and should not be admitted into the appeal proceedings.

In any case, the subject-matter of claim 1 of the main request was inventive when starting from D1. This

document did not disclose a liquid barrier positioned inside the housing as claimed.

This distinguishing feature prevented the travel of liquid to the vacuum connection and ensured that the collection of wound exudate was confined to regions of the device positioned below the wound cover. As a result, the device was modular in that the liquid-retention chamber or the vacuum source could be replaced as needed (paragraph [0052] of the patent) with a reduced risk of contact with potentially dangerous bodily liquids (paragraph [0054] of the patent). The claimed device was particularly convenient for smaller wounds such as those that were under home care. Accordingly, the invention defined by claim 1 of the main request addressed the problem of providing an improved disposable negative pressure wound therapy device for treating this type of wound.

The arrangement of D1 resulted in liquids exiting the housing of the dressing element and entering into the port, where filter 596 was located. Hence, the risk of the user contacting the bodily liquids was increased. The person skilled in the art would have not been prompted or motivated to modify D1 and move the filter to a position that was inside the collection chamber. Furthermore, modifying the device of D1 in such a way would increase the risk that the filter would become occluded by wound exudate as the housing of D1 was intended to collapse under the application of negative pressure (paragraph [0064] of D1) and would also limit the volumetric collection capacity of the collection chamber. The assertion by opponent 2 that the person skilled in the art would have manufactured collection chamber 590 and reduced pressure supply port 596 as a single piece in D1 involved a hindsight analysis. There

was no teaching in D1 that the chamber and the port should be unitarily manufactured. Even if the person skilled in the art had chosen to do so, several options for the positioning of the filter would have still been open.

The subject-matter of claim 1 of the main request was inventive also when starting from D17. This document did not disclose a liquid barrier positioned inside a housing as claimed. D17 disclosed a piece of cotton which simply acted to absorb wound exudate but did not provide any liquid barrier preventing liquid travel from a liquid absorbing structure into a vacuum connection while allowing gas flow. Once the cotton became completely saturated, there was no means to prevent liquid from entering the vacuum connection. There was no motivation, either from D17 alone or in combination with D2, to incorporate a liquid barrier as claimed in the device of D17.

D25 had been filed late and had not been admitted by the Opposition Division. Moreover, D25 was not *prima facie* relevant. The Board should not admit D25 into the appeal proceedings.

Proprietor's request for apportionment of costs

An apportionment of costs against opponent 2 in accordance with Article 16 RPBA 2020 was requested.

The filing of a high number of new objections and further evidence by opponent 2 at a late stage in the proceedings before the Opposition Division and in the subsequent appeal proceedings was contrary to the need for procedural efficiency and amounted to an abuse of

procedure. The proprietor incurred unforeseen costs that could and should have been avoided.

Reasons for the Decision

1. Subject-matter of the patent

The patent in suit relates to a wound therapy device configured to provide negative pressure therapy to a wound. Such a device is typically used to promote healing, especially of chronic wounds.

Two embodiments of a wound therapy device according to the patent are illustrated in Figures 2 and 3, reproduced below.

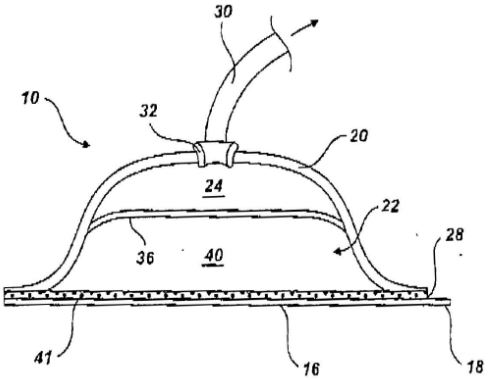


Fig. 2

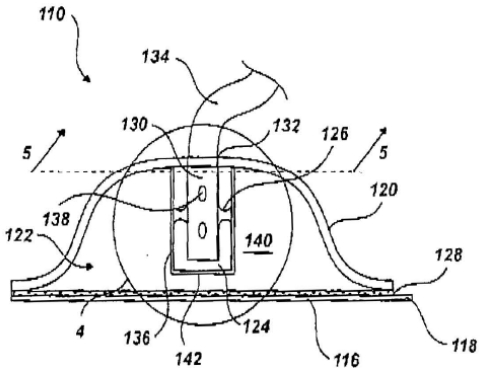


Fig. 3

The device comprises a housing (20, 120), a liquid-retention chamber (40, 140), a liquid absorbing structure comprising super-absorbent polymers within the liquid-retention chamber, a vacuum connection (30, 32, 130, 132) for coupling to a vacuum source and a liquid barrier (36, 136).

The housing comprises a flexible barrier and is configured to cover at least a portion of a wound.

The liquid-retention chamber is positioned inside the housing.

The vacuum connection is in gaseous communication with the liquid-retention chamber.

The liquid barrier is positioned inside the housing and is configured to prevent liquid travel from the liquid absorbing structure into the vacuum connection while allowing gas flow.

According to the patent, the claimed device addresses the need for in-home use by a patient with little supervision and the need for easy portability to allow the travel and mobility of the patient (paragraph [0003]).

2. Extension of subject-matter

The patent is derived from European patent application No. 12008235.9, which is a divisional of European patent application No. 07794746.3 ("the parent application"). The application as filed comprises the description, the drawings and the claims (as "important aspects of the invention", at the end of the description) of the parent application as filed. For the assessment of added subject-matter, it is therefore sufficient to consider the parent application as filed.

2.1 The proprietor argued that some of the objections of added subject-matter raised by opponent 2 had been raised late and should not be admitted into the appeal proceedings. The Board decided to consider these objections and came to the conclusion that they are not

convincing, as explained below.

2.2 Opponent 2 argued that the parent application as filed disclosed the feature of a housing configured to cover at least a portion of a wound with a liquid-retention chamber and a liquid absorbing structure, only as a "rigid or semi-rigid housing" or supported by structural supports. However, as pointed out by the proprietor, claim 1 and paragraph [21] of the parent application as filed disclose the housing in general terms. The liquid absorbing structure as defined in claim 1 of the main request is not inextricably linked with any additional features concerning the rigidity of the housing or structural supports. These additional features would contribute to the creation of the claimed liquid-retention chamber. However, claim 1 of the parent application as filed defines the liquid-retention chamber without these additional features.

2.3 Opponent 2 argued that claim 1 of the main request did not define a vacuum connection separated from the liquid-retention chamber by a liquid barrier. However, the claim specifies that the liquid barrier prevents the travel of liquid while allowing gas flow from the liquid absorbing structure, within the liquid-retention chamber, into the vacuum connection. This implies that the liquid barrier keeps the liquid in the liquid-retention chamber and separates this chamber from the vacuum connection.

2.4 In the impugned decision, the Opposition Division considered that the parent application as filed did not provide a basis for the general definition in claim 1 of the main request that the liquid barrier was positioned inside the housing without defining a vacuum chamber and specifying that the liquid barrier

subdivided the internal space of the housing into the vacuum chamber and the liquid-retention chamber. The opponents shared the Opposition Division's view.

Claim 1 of the main request is generally based on claim 1 of the parent application as filed, with the addition of the feature of the liquid absorbing structure being disclosed in paragraph [29] and the liquid barrier positioned inside the housing being disclosed in Figures 2 (liquid barrier 36 within housing 20) and 3 (liquid barrier 136 within housing 120) together with paragraphs [24] and [37] of the parent application as filed.

While the embodiment of Figure 2 comprises both a liquid barrier as claimed and a vacuum chamber within the housing, paragraph [28] of the parent application as filed explains that the liquid barrier in that embodiment *"serves to prevent travel of liquid form the liquid retention chamber 40 to the vacuum connection 30"*.

The embodiment of Figure 3 discloses a different arrangement for the same function in which the liquid barrier consists of a vacuum chamber acting as a droplet gap (paragraph [37] of the parent application as filed). According to paragraph [38] of the parent application as filed, the embodiment of Figure 2 could be modified to take advantage of the droplet-gap principle illustrated in Figure 3. Irrespective of whether the embodiment of Figure 3 could be considered not to comprise a vacuum chamber within the housing (the vacuum chamber itself serves as a liquid barrier in that embodiment) and the specific nature of the liquid barrier in that embodiment, according to paragraph [37] of the parent application as filed, the

liquid barrier must be positioned between the liquid-retention chamber and the vacuum connection "*to prevent liquids from travelling from the liquid-retention chamber 140 to the vacuum passage 130*".

The argument of opponent 1 that the vacuum chamber was required to distribute the reduced pressure across the area of the liquid barrier is not convincing. The parent application as filed does not mention such an alleged requirement. From the parent application as filed, the person skilled in the art derives, instead, that the position of the liquid barrier within the housing, independently of whether a vacuum chamber is present, makes it more convenient to have modular embodiments of the wound therapy device in which only the liquid-retention chamber may be replaced (as discussed in paragraphs [64] and [66]). This is because the liquid-retention chamber can be safely replaced by separating the housing from the vacuum connection and disposing of the whole housing without the need to manipulate other components which have been in contact with bodily fluids.

It follows that the liquid barrier and a vacuum chamber within the housing are not disclosed in the parent application as filed as a necessary combination for achieving a certain technical effect. Hence, these elements are not inextricably linked, irrespective of whether there may be a structural relationship between the liquid barrier and the vacuum chamber on one of its sides in the embodiment in Figure 2.

Opponent 2 argued further that the liquid barrier as defined in claim 1 of the main request had been disclosed in addition to a rigid or semi-rigid housing and with the liquid barrier in the form of a porous

hydrophobic film. These additional features could not be omitted.

As regards the omission of the rigid or semi-rigid housing, claim 1 and paragraph [21] of the parent application as filed provide a basis for the claim without this feature of the housing. The more specific definition of the liquid barrier in claim 1 of the main request compared with its definition in claim 1 of the parent application as filed does not entail features inextricably linked with the housing. As regards the omission of the definition of the liquid barrier as a porous hydrophobic film, paragraph [28] of the parent application as filed to which the proprietor referred discloses various other possible forms of a liquid barrier, which may include "*a porous hydrophobic film, a porous hydrophobic structure, a droplet gap or a labyrinth*". Moreover, paragraph [28] also discloses that "*other technologies that allow gas flow but prevent liquid flow may also be used as suitable liquid barriers*".

2.5 As the proprietor pointed out, the features of the porous structure as defined in claims 6 and 7 of the main request are based on claim 12 and paragraph [29] of the parent application as filed. Especially paragraph [29] makes clear that the porous structure, which has the function of retaining liquids, belongs to the liquid absorbing structure within the liquid-retention chamber.

2.6 Paragraph [5] and claim 2 of the parent application as filed disclose a seal in addition to a liquid barrier. Hence, these entities are disclosed as distinct entities as defined in claim 15 of the main request.

2.7 Claim 16 of the main request refers to a vacuum chamber without specifying its position in the device. For the same reasons as those given for the definition in claim 1 of the main request of the liquid barrier positioned inside the housing without defining the vacuum chamber, the location and shape of the vacuum chamber, whether it is downstream or upstream of the vacuum connection, are not inextricably linked with the other features of claim 16 of the main request.

2.8 In conclusion, the opponents' objections of added subject-matter under Articles 76(1) and 123(2) EPC do not prejudice the maintenance of the patent on the basis of the main request.

3. Novelty

3.1 Opponent 2 argued that the subject-matter of claim 1 of the main request was not novel over D2.

D2 discloses a wound therapy device configured to provide negative pressure therapy to a wound. Figure 1a, referred to by opponent 2, is reproduced below.

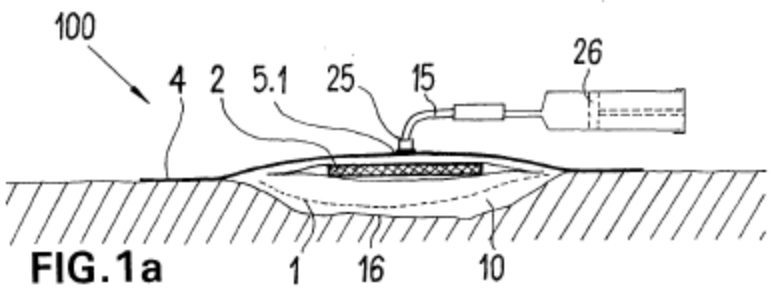


FIG.1a

The wound therapy device comprises a housing in the form of a somehow rigid wound covering member (4, paragraph [0033]). The housing is configured to cover at least a portion of a wound, as shown in the figure.

The wound therapy device further comprises a liquid-retention chamber positioned inside the housing and a vacuum connection (5.1) for coupling to a vacuum source (syringe 26) in gaseous communication with the liquid-retention chamber.

Opponent 2 essentially argued that absorbing body 2 was both a liquid absorbing structure and a liquid barrier within the meaning of claim 1 of the main request.

However, the claim requires a liquid absorbing structure and a liquid barrier preventing the travel of liquid from the liquid absorbing structure. Hence, on a plain reading of the claim, in accordance with the disclosure of the patent as a whole and contrary to the arguments of opponent 2, the liquid barrier and the liquid absorbing structure must be separate entities.

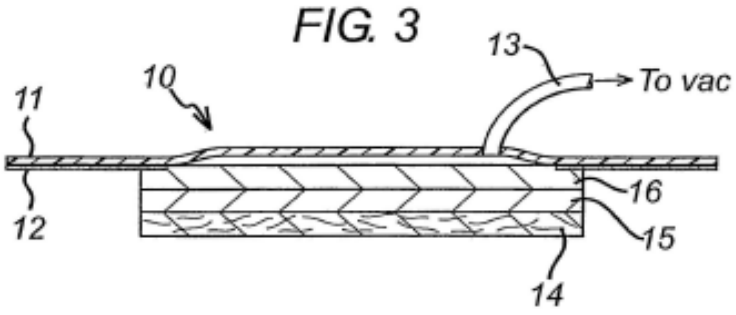
D26 and D27, referred to by opponent 2 to explain that a single product member can fulfil two or more functions (which is not contested), and not admitted by the Opposition Division in the impugned decision, cannot change the plain meaning of the claim. Hence, the Opposition Division was correct to consider them to lack *prima facie* relevance and not to admit them into the proceedings. Article 12(6) RPBA prescribes that the Board must not admit evidence which was not admitted in the proceedings leading to the decision under appeal unless the decision not to admit it suffered from an error in the use of discretion or the circumstances of the appeal case justify its admittance. Under this article, D26 and D27 are not admitted into the appeal proceedings.

Consequently, the subject-matter of claim 1 of the main request is novel over D2 by virtue of the liquid

barrier positioned inside the housing.

3.2 Opponent 2 argued that the subject-matter of claim 1 of the main request was not novel over D4.

D4 discloses a wound therapy device configured to provide negative pressure therapy to a wound. Figure 3, referred to by opponent 2, is reproduced below.



The wound therapy device comprises a cover sheet (11) which is configured to cover at least a portion of a wound. The device further comprises a screen structure with several layers (14, 15 and 16) and a vacuum connection (13) for coupling to a vacuum source ("To vac").

Opponent 2 argued that cover sheet 11 was a housing, inside of which there was a liquid-retention chamber with a liquid absorbing structure and a liquid barrier. It identified the liquid barrier as liquid-absorbent layer 16, possibly together with the water-permeable, size exclusion membrane disclosed on page 20, lines 5 to 8 of D4.

The Board shares the proprietor's view that D4 does not disclose a liquid barrier configured to prevent liquid travel from a liquid absorbing structure into the vacuum connection while allowing gas flow.

In this respect, D4 is similar to D2. What retains liquid within the housing of D4 are layers 14 and 16 (page 19, line 28 to page 20, line 8), which are to be identified as the liquid absorbing structure within the meaning of claim 1 of the main request. Layers 15 and 16 are separated by a water-permeable, size exclusion membrane (page 20, lines 5 to 8). As explained for D2, claim 1 of the main request defines a liquid absorbing structure and a liquid barrier as separate entities. If layer 16 belongs to the liquid absorbing structure, it cannot be considered, additionally, a liquid barrier within the meaning of the claim. The size exclusion membrane alone cannot be considered to be the claimed liquid barrier because it is water permeable. As regards the reference of opponent 2 to the embodiment of Figure 11 of the patent, the liquid-retention chamber according to that embodiment may be filled with absorbent material (paragraph [0050]). However, a separate liquid barrier, indicated as 36 in Figure 2, is present in the embodiment of Figure 11 too.

As regards the arguments of opponent 2 with reference to D11, the Board notes that the decision of the German Federal Patent Court concerned a different claim and, although of authoritative value, is not binding on the Board. After considering that decision, the Board cannot reach the conclusion that liquid-absorbent layer 16 anticipates a liquid barrier as defined in claim 1 of the main request for the reasons explained above.

In summary, the subject-matter of claim 1 of the main request is novel over D4 by virtue of the liquid barrier positioned inside the housing.

3.3 Opponent 2 argued that the subject-matter of claim 1 of the main request was not novel over each of D12, D14, D15, D16 and D24.

These documents were filed after the opposition period and were not considered by the Opposition Division in the impugned decision. Under Article 12(4) RPBA, their admittance into the appeal proceedings is at the Board's discretion unless opponent 2 demonstrates that the objections based on these documents were admissibly raised and maintained in the proceedings leading to the decision under appeal.

In the preliminary opinion sent with the summons to oral proceedings, the Opposition Division held that D12 and D14 to D16 did not appear to be *prima facie* relevant for the novelty of claim 1 and should not be admitted into the proceedings (point 12.1 of the opinion). The reason for the lack of *prima facie* relevance was that these documents did not appear to disclose a liquid absorbing structure and a liquid barrier as separate entities. Hence, there is no demonstration, but rather strong doubts, that these documents would have been admitted by the Opposition Division. As regards the *prima facie* relevance of the documents, the Board agrees with the Opposition Division's conclusions for the reasons it provided.

As regards D24, the Opposition Division did not decide on its admittance (point 10 of the Reasons of the impugned decision). D24 is not, *prima facie*, more relevant than the other documents in the proceedings as it does not appear to disclose a liquid barrier as claimed. D24 describes a layer of material in proximity of a wound to be treated (layer 227, Figure 2) as a manifold layer which assists in distributing reduced

pressure (paragraph [0066]). It may also be used to distribute fluid. There is no disclosure that this layer should be configured to prevent liquid travel from a liquid absorbing structure into a vacuum connection, irrespective of its thickness, as referred to by opponent 2. Hence, the layer of material is not a liquid barrier as defined in claim 1 of the main request. Hence, there is no demonstration that the objection based on D24 was admissibly raised in the proceedings leading to the decision under appeal.

3.4 For these reasons, D12, D14 to D16 and D24 are not admitted into the appeal proceedings under Article 12(4) RPBA.

3.5 In conclusion, the novelty objections (Article 54 EPC) raised by opponent 2 do not prejudice the maintenance of the patent on the basis of the main request.

4. Inventive step

4.1 The opponents argued that the subject-matter of claim 1 of the main request was not inventive when starting from D1. The proprietor submitted that the objection raised by opponent 1 starting from D1 should not be admitted into the appeal proceedings. The Board decided to take this objection into consideration. As explained below, however, it is not convincing.

The embodiment of Figure 6 of D1 (reproduced below and which the opponents referred to) discloses a wound therapy device configured to provide negative pressure therapy to a wound.

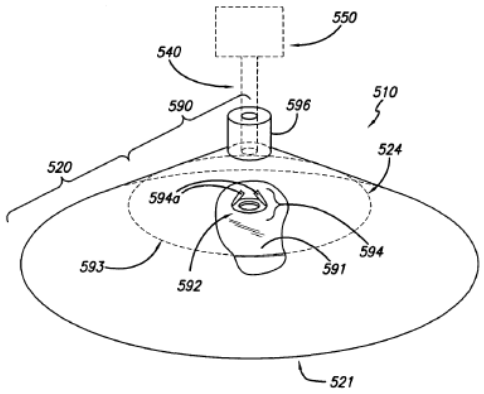


FIG. 6

The device comprises a housing including a flexible overlay (520) and an attached collection chamber (590, which may have a rigid or semi-rigid structure - sentence spanning the left and the right column on page 20) positioned inside the housing. The housing is configured to cover at least a portion of a wound. The device further comprises a vacuum connection (540 and 596) for coupling to a vacuum source (vacuum system 550), which is in gaseous communication with the liquid-retention chamber, and a liquid barrier (the micropore or hydrophobic filter mentioned in paragraph [0064]) which prevents the travel of liquid from the liquid-retention chamber to the vacuum connection while allowing gas flow.

The opponents argued that D1 also disclosed that the liquid barrier was positioned inside the housing because pressure supply port 596, within which the micropore or hydrophobic filter was positioned, had to be considered a part of the housing.

The Board shares the Opposition Division's view that pressure supply port 596 is not part of the housing. It is part of the vacuum connection since it is described "*to operably connect the reduced pressure supply means 540 to the collection chamber 590*" (paragraph [0064]).

As derivable from Figure 6, pressure supply port 596 is positioned above the collection chamber as a separate element with a specific function and does not contribute to enclosing the liquid-retention chamber. The argument of opponent 2 that the collection chamber and the port were a single piece is not convincing. Nowhere is this disclosed in D1. Moreover, even if this were the case, pressure supply port 596 would still not have the function of a housing for containing the liquid-retention chamber.

Since pressure supply port 596 is not part of a housing according to claim 1 of the main request, the subject-matter of the claim is distinguished over D1 by virtue of the liquid barrier positioned inside the housing.

Opponent 1 argued that this distinguishing feature was a trivial matter of design since it did not solve any technical problem over the arrangement of D1. The liquid barrier would perform precisely the same function whether it was positioned in an outlet of the housing in the form of a pressure supply port or just within the housing itself, for example, across the mouth of the outlet.

The Board, however, shares the proprietor's view that a liquid barrier as defined in claim 1 of the main request has the technical effect of preventing the travel of liquid to the vacuum connection, ensuring that wound exudate is confined to regions of the device positioned below the wound cover. This makes it possible to have modular embodiments of the wound therapy device in which only the liquid-retention chamber may be replaced by separating the housing from the vacuum connection. The housing can then be disposed of and the vacuum connection can be reused without the

need for manipulating, replacing or sterilising other components which have been in contact with bodily fluids. In D1, instead, as opponent 1 pointed out, the pressure supply port would have to be replaced together with the housing.

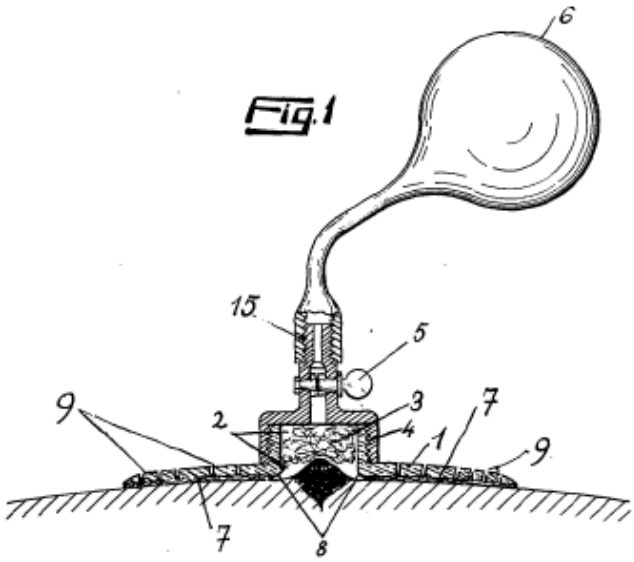
In conclusion, the distinguishing feature solves the objective technical problem of providing a device which is safer and easier, especially for home use.

The problem proposed by opponent 2 based on the alleged advantages of manufacturing different components as a single piece, i.e. to improve the reliability and durability of the wound therapy device, is neither expressly taught nor derivable from the patent in suit. The patent mentions modular arrangements instead, this speaking against manufacturing distinct functional components together.

The person skilled in the art would not have received any suggestion, in particular from common general knowledge, to implement the distinguishing feature into the wound therapy device of D1 to solve the objective technical problem. Moreover, as the proprietor pointed out, it is at least not excluded that the housing of D1 may collapse in use. This would entail the risk that a liquid barrier positioned inside the housing may be brought into contact with the wound and become occluded by wound exudate. Also for this reason the person skilled in the art would not have been motivated to change the position of the liquid barrier in the device of D1 as defined in claim 1 of the main request.

4.2 Opponent 2 argued that the subject-matter of claim 1 of the main request was not inventive when starting from D17.

The embodiment of Figure 1 of D17 (reproduced below and which opponent 2 referred to) discloses a wound therapy device configured to provide negative pressure therapy to a wound.



The device comprises a housing (disc 1) comprising a central cylindrical section onto which a cap (4) is screwed. The central cylindrical section and the cap delimit a chamber (2) containing a piece of cotton (3) to absorb pus from the wound (page 1, first paragraph). As opponent 2 argued, the piece of cotton is a liquid absorbing structure arranged within a liquid-retention chamber. The cap comprises a channel and an outer thread (15) onto which a vacuum source (6) can be screwed (page 1, fifth paragraph). This is a vacuum connection for coupling to a vacuum source that is in gaseous communication with the liquid-retention chamber.

Opponent 2 argued that the piece of cotton was also a liquid barrier according to claim 1 of the main request. However, as explained for D2, the claim defines a liquid absorbing structure and a liquid

barrier as separate entities. Moreover, there is no disclosure in D17 that the piece of cotton would, as such, prevent liquid travel into the vacuum connection while allowing gas flow. As the proprietor submitted, at least when the piece of cotton becomes saturated, there is no means to prevent liquid from entering the vacuum connection.

It follows that the subject-matter of claim 1 of the main request is distinguished over D17 by virtue of the liquid barrier positioned inside the housing.

The objective technical problem solved by this distinguishing feature, as explained for D1, is to provide a device which is safer and easier, especially for home use. The problem proposed by opponent 2, related to an extension of the possible period of negative pressure wound therapy, is not related to the position of the liquid barrier as claimed.

If the person skilled in the art had replaced the piece of cotton of D17 with super-absorbent polymers, as suggested by opponent 2, this would still have not resulted in a liquid barrier inside the housing as defined in claim 1 of the main request.

Neither in D2 nor D17 is there any teaching to add the absorbent body disclosed in D2 anywhere in the device of D17 for the solution of the objective technical problem.

4.3 Opponent 2 argued that the subject-matter of claim 1 of the main request was not inventive when starting from D25.

D25 was filed after the opposition period and was not

considered by the Opposition Division in the impugned decision. Under Article 12(4) RPBA, its admittance into the appeal proceedings is at the Board's discretion unless opponent 2 demonstrates that the objection based on this document was admissibly raised and maintained in the proceedings leading to the decision under appeal.

The Opposition Division did not decide on the admittance of D25 (point 10 of the Reasons of the impugned decision). D25 is not *prima facie* more relevant than the other documents in the proceedings as it does not disclose a liquid barrier as claimed. Cup 138 in Figure 5, referred to by opponent 2, does not prevent the travel of liquid from a liquid absorbing structure to a vacuum connection while allowing gas flow. Hence, there is no demonstration that the objection based on D25 was admissibly raised in the proceedings leading to the decision under appeal.

For these reasons, D25 is not admitted into the appeal proceedings under Article 12(4) RPBA.

4.4 In conclusion, the objections of lack of inventive step (Article 56 EPC) raised by the opponents do not prejudice the maintenance of the patent on the basis of the main request.

5. Proprietor's request for apportionment of costs

The proprietor requested an apportionment of costs against opponent 2, in essence because the late filing of several objections was contrary to the need for procedural efficiency and was an abuse of procedure.

However, the Board considers that the repetitive filing

of the new objections and evidence does not amount to an abuse of procedure but is an acceptable procedural strategy. Such a strategy remains within the legitimate interest and freedom of opponent 2 to present its case as it wishes, although the Board doubts that it may be effective for reaching the opponent's objective.

It was then for the Board to decide whether to admit the late-filed objections and evidence, in view of, *inter alia*, the need for procedural efficiency.

Hence, the proprietor's request for apportionment of costs against opponent 2 must be rejected (Article 16(1) RPBA and Article 104(1) EPC).

6. As none of the opponents' objections prejudices the maintenance of the patent according to the main request, the patent must be so maintained (Article 101(3)(a) EPC).

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The patent is maintained as granted.

3. The request for apportionment of costs against opponent 2 is rejected.

The Registrar: The Chairman:

A. Chavinier-Tomsic M. Alvazzi Delfrate

Decision electronically authenticated