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**Datasheet for the decision  
of 19 September 2024**

**Case Number:** T 2074/21 - 3.3.10

**Application Number:** 11802142.7

**Publication Number:** 2773383

**IPC:** A61L2/00, A61M1/00

**Language of the proceedings:** EN

**Title of invention:**  
REDUCED PRESSURE THERAPY APPARATUSES

**Patent Proprietor:**  
Smith & Nephew PLC

**Opponent:**  
KCI Licensing Inc.

**Headword:**

**Relevant legal provisions:**  
EPC Art. 54, 56, 84, 123(2)

**Keyword:**

Novelty - (yes)

Inventive step - (yes)

Amendments - allowable (yes)

Clarity - objection not open for examination in appeal, feature already in claim as granted

**Decisions cited:**

G 0003/14

**Catchword:**



**Beschwerdekammern**  
**Boards of Appeal**  
**Chambres de recours**

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Case Number: T 2074/21 - 3.3.10

**D E C I S I O N**  
**of Technical Board of Appeal 3.3.10**  
**of 19 September 2024**

**Appellant:** Smith & Nephew PLC  
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**Representative:** Appleyard Lees IP LLP  
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**Respondent:** KCI Licensing Inc.  
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**Decision under appeal:** **Decision of the Opposition Division of the  
European Patent Office posted on 24 September  
2021 revoking European patent No. 2773383  
pursuant to Article 101(3) (b) EPC.**

**Composition of the Board:**

**Chairman** P. Gryczka  
**Members:** A. Zellner  
L. Basterreix

## **Summary of Facts and Submissions**

- I. The patent proprietor lodged an appeal against the decision of the opposition division to revoke the European patent No. 2 773 383 (Article 101(3) (b) EPC).
- II. Notice of opposition has been filed on the basis of Article 100(a) EPC for lack of novelty and lack of inventive step (Articles 54 and 56 EPC), and Article 100(c) EPC for added subject-matter.
- III. Reference is made to the following documents:
- D2: CN 201953601 U
  - D2a: English machine translation of D2
  - D15: US 2009/0299306 A1
  - D16: US 2009/0312723 A1
  - D21: US 2011/0028921 A1
- IV. In the opposition proceedings, the appellant defended the patent in amended form. The opposition division held that claims 1 to 3, 6, 7, 9 and 11 of the main request did not contain subject-matter which extended beyond the content of the application as filed (Article 123(2) EPC), and that claim 1 of this request also met the requirements of Article 84 EPC. The opposition division furthermore considered the pump assembly according to claim 1 to be novel in view of the disclosure of documents D1 to D4 as well as D15 (Article 54 EPC). The pump assembly was, however, found not to be based on an inventive step (Article 56 EPC). The disclosure of document D15 was considered to be the closest prior art.

Auxiliary request 1 before the opposition division was

considered not to be allowable for the same reason as the main request (Article 56 EPC).

The opposition division admitted auxiliary request 2 into the proceedings, but considered the request not to be allowable for lack of inventive step, for the same reason as the main request (Article 56 EPC).

Auxiliary request 3 before the opposition division was not admitted into the proceedings. It was considered not to be *prima facie* allowable (Article 56 EPC).

The opposition division admitted documents D15, D16 as well as D19 to D21 into the proceedings, but not documents D17 and D18. These were considered not to be more relevant than D16.

V. The patent proprietor appealed this decision and argued that the opposition division erred in their decision when holding the pump assembly according to claim 1 of the main request and of auxiliary request 2 not to be based on an inventive step (Article 56 EPC). The appellant also submitted that the opposition division's decision not to admit auxiliary request 3 into the proceedings was erroneous.

VI. Claims 1 and 2 of the main request are relevant for this decision. They have the following wording:

*"1. A pump assembly (104, 1000) for reduced pressure wound therapy, comprising:  
a housing (120, 1020);  
a pump (232, 1090) supported within or by the housing, the pump comprising:  
a motor (1092);  
an inlet (250) and an outlet (252);*

*a first valve configured to control a flow of a fluid through the inlet; and  
a second valve configured to control a flow of a fluid through the outlet;  
a flow pathway through the pump assembly; and  
characterized in that*

*a one-way flow valve (246, 1030) is in fluid communication with the pump and supported within a manifold (240) that is disposed in the housing and sealingly coupled to the inlet of the pump, the one-way flow valve being configured to substantially prevent a flow of gas through the flow pathway in a direction of flow away from the pump,*

*wherein the pump assembly has been sterilized such that at least an inside and an outside of the housing, the flow pathway, the first and second valves, and the pump have been sterilized."*

*"2. The pump assembly of claim 1, wherein the first and second valves are configured to permit a flow of sterilization gas through the first and second valves during sterilization process."*

VII. The appellant argued essentially as follows:

The respondent's objection of lack of clarity should not be admitted into the proceedings, because it relates to a feature which was already present in claim 1 of the patent as granted. Claims 1 and 2 of the main request are based on the application as filed, in particular on claims 1 and 7 and paragraphs [0102] and [0056]. The claimed subject-matter is novel in view of the disclosure of document D15, and is also based on an inventive step considering D15 to be the closest prior art. The main request thus meets the requirements of Articles 84, 123(2), 54 and 56 EPC.

VIII. The respondent argued essentially as follows:

Claim 1 of the main request does not meet the requirements of Article 84 EPC. The claim was amended post-grant, and it is the added feature which leads to a lack of clarity. Claims 1 and 7 of the main request are not allowable because they are not based on the application as filed. Both claims are the result of intermediate generalisations (Article 123(2) EPC). The main request is also not allowable because the claimed subject-matter is not novel in view of document D15 (Article 54 EPC), and is not based on an inventive step considering document D15 as the closest prior art (Article 56 EPC).

IX. Oral proceedings before the board were held on 19 September 2024. The decision was announced at the end of the proceedings.

X. The appellant (patent proprietor) requests that the decision of the opposition division be set aside and the patent be maintained on the basis of the main request, or as an auxiliary measure on the basis of auxiliary requests 1 to 4. The main request is identical to the main request underlying the impugned decision, auxiliary requests 1 and 2 were filed as auxiliary requests 2 and 3 during the opposition proceedings on 19 March 2021 and 19 May 2021, respectively. Auxiliary requests 3 and 4 were filed on 7 June 2024.

XI. The respondent (opponent) requests that the appeal be dismissed and that auxiliary requests 2 to 4 not be admitted into the proceedings.

## **Reasons for the Decision**

1. The appeal is admissible.

### *Main request*

#### *Clarity (Article 84 EPC)*

2. In the contested decision, the opposition division came to the conclusion that claim 1 of the main request met the requirements of Article 84 EPC. According to the opposition division the disclosure of paragraph [0076] of the description of the patent as granted made it clear that a closed fluid coupling was intended, rather than a sealing against bacteria, and that it was the one-way flow valve to which the inlet of the pump was sealingly coupled. Both of the respondent's arguments were thus dismissed.
3. According to the respondent, claim 1 of the main request was unclear, because the wording of the claim allowed for the inlet of the pump being "*sealingly coupled*" to the "*one-way flow valve*", to the "*manifold*", or to both of them. All of these options made technical sense, and the claim lacked clarity since it was unclear which of these options were intended. The respondent also argued that the objection should be admitted into the appeal proceedings because, although only the term "*sealingly*" was added into claim 1 during the opposition proceedings, it was this term which introduced a lack of clarity, because it gave a more precise meaning as to the level of the coupling.



4. The appellant argued that the objection should not be admitted. According to the appellant, the only amendment with respect to claim 1 as granted was the addition of the term "*sealingly*". The opponent's objection, however, did not concern the nature of the coupling, *i.e.* "***sealingly coupled***", but the alleged ambiguity as to which component was intended to be "*sealingly coupled to the inlet of the pump.*" As a consequence, it was not the amendment with respect to claim 1 as granted which introduced the alleged ambiguity. The appellant concluded, by reference to G3/14, that the amendment was consequently not open to an objection under Article 84 EPC.
  
5. The board observes the following:
  - 5.1 The respondent's argument that the lack of clarity arose from introducing the additional feature "*sealingly*" - defining the type of "*coupling*" - into claim 1 is not convincing, since the respondent argued that it was not clear to which part of the pump assembly the inlet of the pump was coupled, and not from the fact that it was coupled "*sealingly*". The respondent's objection does therefore, as submitted by the appellant, concern a feature which was already part of claim 1 of the patent as granted. The board thus comes to the conclusion that the objection based on Article 84 EPC is not allowable (G3/14).
  
  - 5.2 The board also notes, and agrees with the opposition division's conclusion, that it is the "*... manifold (240) that is disposed in the housing and sealingly coupled to the inlet of the pump, ...*". This is also supported by paragraph [0076] and Figure 4A of the patent as granted.

*Amendments (Article 123(2) EPC)*

6. The opposition division came to the conclusion that the main request met the requirements of Article 123(2) EPC. The opposition division considered claim 1 of the main request to be based on claims 1 and 7, and paragraph [0102], and claim 2 to be based on paragraph [0056], respectively, of the application as filed. The respondent did not agree and argued that claims 1 and 2 violated the requirements of Article 123(2) EPC.
7. According to the respondent, only part of paragraph [0102] of the application as filed has been added to claim 1. Only the feature *"... and supported within a manifold 240 that is disposed in the housing and sealingly coupled to the inlet of the pump, ..."* of paragraph [0102] has been added, but not the feature *the "... manifold 240 and/ or the one-way valve 246 can be in communication with the connector 128 ..."*. Since, however, these features were linked, the amendment was an unallowable intermediate generalisation.
8. The respondent further argued that claim 2 of the main request did not find a basis in the application as filed, since paragraph [0056] did not specify which of the pump valves of claim 1 were configured to permit a flow of sterilization gas through them during the sterilization process, whereas - according to amended claim 2 - the first and second valves were configured in that way. The respondent also argued that, according to paragraph [0056], the pump valves were configured to permit sufficient flow of sterilization gas such that the entire fluid pathway within the pump could be exposed to the sterilization gas. This feature, however, was omitted from claim 2.

9. The board comes to the following conclusions:

*Claim 1*

9.1 Claim 1 comprises, in addition to the features of claims 1 and 7 of the application as filed, the feature that a one-way flow valve, which is in fluid communication with the pump, is *"... supported within a manifold (240) that is disposed in the housing and sealingly coupled to the inlet of the pump, ..."*. The board notes that this feature as such is disclosed in paragraph [0102] of the application as filed. This was not disputed. The parties disagreed whether the feature is only disclosed in combination with the presence of *"the connector 128"*.

9.2 According to paragraph [0102] of the application as filed, the presence of connector 128 is not mandatory for an embodiment wherein manifold 240 is disposed in the housing and sealingly coupled to the inlet of the pump. The first sentence of paragraph [0102] discloses that the *"manifold 240 and/or the one-way flow valve 246 **can be** in communication with the connector 128"* (emphasis added by the board). In addition, according to the term *"in some embodiments"* used at the beginning of the second sentence of paragraph [0102], it is clear that the connector 128 is not necessarily present for each embodiment. It may in particular not be present when the manifold 240 is sealingly coupled with the inlet port or connector 250 in the pump 232, as further disclosed in sentence 2 of paragraph [0102]. There is thus no mandatory link between the features referred to by the respondent.

9.3 Claim 1 of the main request is thus based on the application as filed.

*Claim 2*

9.4 According to claim 2 of the main request, which is dependent on claim 1, the first and second valves (configured to control a flow of a fluid through the inlet or outlet, respectively - see claim 1) are configured to permit a flow of sterilization gas through the first and second valves during sterilization process.

9.5 Paragraph [0056] of the application as filed discloses that the pump can, in some embodiments, *"... be configured to be amenable to gas sterilization, having features, components and other characteristics that make the pump amenable to full sterilization gas exposure and penetration throughout the components of the pump."* The paragraph continues with exemplary embodiments and discloses that *"... one or more pump valves have been selected or configured to permit sufficient flow of sterilization gas therethrough such that the entire fluid pathway within the pump can be exposed to the sterilization gas. (...) in some embodiments, the pump can have other components, such as (...) one way flow valves, to complement the other valves within the pump, ..."*.

9.6 This part of the description discloses that the one way flow valves, if present to complement the other valves within the pump, are not necessarily the ones referred to earlier in paragraph [0056], *i.e.* the pump valves configured to permit sufficient flow of sterilization gas. The specification of the first and second valves in claim 2, *i.e.* pump valves according to claim 1, is

thus based on paragraph [0056] of the description as filed.

9.7 Paragraph [0056] also discloses that the pump valves *"... permit a sufficient flow of sterilization gas therethrough such that the entire fluid pathway within the pump can be exposed to the sterilization gas."* This part, however, is redundant in the context, since the first and second valves are positioned at the inlet and outlet of the pump, respectively, and a flow through these valves necessarily permits a flow of sterilization gas throughout the fluid pathway within the pump.

9.8 Claim 2 of the main request is thus based on the application as filed.

10. The amended claims of the main request therefore meet the requirements of Article 123(2) EPC.

*Novelty (Article 54 EPC)*

11. The opposition division came to the conclusion that the pump assembly according to claim 1 of the main request was novel in view of the disclosures of documents D1 to D4 and D15.

12. The respondent maintained the view that claim 1 of the main request lacked novelty in view of the disclosure of document D15. According to the respondent, D15 disclosed a pump assembly, which also comprised *"... a second valve configured to control a flow of a fluid through the outlet, ..."* of a pump, and wherein the pump assembly had been sterilized such that *"... an inside ..."* of the housing had also been sterilized. The opposition division did not see either of these

features disclosed in document D15 (see points 3.11.1 and 3.12.3 of the impugned decision).

- 12.1 Concerning the first of these features, the respondent argued that a (reciprocating) powered pump implicitly comprised a first and a second valve. The respondent further argued, by reference to paragraphs [0035] and [0039] of document D15, that several of the valves disclosed in that document also satisfied the requirements of the first and second valves according to claim 1 of the main request.
- 12.2 Concerning the second feature, relating to sterilization of an inside of the pump assembly, the respondent argued, by reference to paragraphs [0004] and [0043] of D15, that the pump module disclosed in this document was sterilized. It was also argued, by reference to paragraphs [0062] and [0063] of the patent in suit, that an unsealed gap of the pump housing around the connector 128 allowed for sterilization of the outside, as well as the inside of the housing 120. According to the respondent, this also corresponded to a situation as disclosed in figure 3 and paragraph [0042] of document D15, when the control module and the pump module were separated for sterilization, allowing for sterilization gas to reach the outside, but also to enter the inside of the housing.
13. The appellant submitted that additional features of claim 1, which were not identified by the opposition division as differing features, were also not disclosed for the pump assembly of document D15. It was referred to the features "*... a first valve configured to control a flow of a fluid through the inlet ...*" of the pump and "*... a one-way flow valve (246, 1030) is in fluid communication with the pump and supported within*

*a manifold (240) ...".*

13.1 Concerning the first of these features, the appellant argued, by reference to figure 4 of D15, that port 14 was not an inlet to the pump 106, and that the solenoid valve 118 was not a first valve according to claim 1 of the main request.

13.2 Concerning the second feature, the appellant argued that figure 4 of document D15 did not show how components of the pump module 100 were fluidly connected to one another. The appellant further submitted that document D15 did not disclose a manifold, in particular not in combination with a one-way flow valve supported therein.

14. The board observes the following:

14.1 Document D15 discloses a pump assembly for reduced pressure wound therapy (see in particular figures 1 and 4 and paragraph [0002]). Neither the figures, nor the description of D15 disclose detailed information on the components and their arrangement within the pump assembly. The document discloses, however, a pump assembly comprising three valves, *i.e.* "a quick release valve 18" (see figure 1 and paragraph [0035]), "a check valve 110" (see figure 4 and paragraph [0037]) and "a solenoid valve 118" (see figure 4 and paragraph [0039]).

14.2 Claim 1 of the main request relates to a pump assembly which also comprises three valves, *i.e.* "a first valve configured to control a flow of a fluid through the inlet" (250) of a pump, "a second valve configured to control a flow of fluid through an outlet" (252) of a pump, and "a one-way flow valve (246, 1030) in fluid

*communication with the pump and supported within a manifold (240) that is disposed in the housing and sealingly coupled to the inlet of the pump, the one-way valve being configured to substantially prevent a flow of gas through the flow pathway in a direction of flow away from the pump".*

- 14.3 The parties disagreed in particular concerning the disclosure of the features "*... a one-way flow valve (246, 1030) is in fluid communication with the pump and supported within a manifold (240) ...*" and "*... wherein the pump assembly has been sterilized such that at least an inside (...) of the housing (...) have been sterilized.*"
- 14.4 The respondent pointed out that figure 4 of document D15 disclosed a manifold.
- 14.5 The board comes to the conclusion that document D15 discloses a pump assembly comprising a manifold, which is - as acknowledged by the appellant - a branching in a circuit (see the component located above pump 106 in figure 4 of document D15). However, none of the three valves disclosed in D15 is supported within this manifold. Claim 1 of the main request, however, requires that the one-way flow valve is supported within a manifold.
- 14.6 The respondent argued that the valves disclosed in D15 correspond to the valves comprised in the pump assembly according to claim 1 of the main request.
- 14.7 The board comes to the conclusion that this is not the case.



- 14.7.1 Claim 1 of the main request requires the presence of a one-way valve. A valve allows - when open - fluid to flow in a direction from higher pressure to lower pressure. The direction of flow is thus determined by the pressure difference between two sides of the valve, but not necessarily by the valve itself. A one-way valve will allow fluid to flow only in one direction. Not every valve is a one-way valve.
- 14.7.2 Document D15 discloses three different valves (see point 14.1 of this decision).
- 14.7.3 A first valve - the "*quick release valve 18*" - is intended to mean a valve or connection point that will allow the apparatus 10 to communicate negative pressure to a negative pressure wound therapy dressing (see paragraph [0035] and figure 1). Document D15 does not disclose that this valve is designed as a one-way valve.
- 14.7.4 The pump assembly disclosed in D15 comprises a second valve - the "*check valve 110*" - for preventing flow of positive pressure from the pump module 100 to the dressing. (see paragraph [0037] and figure 4). Document D15 does not disclose that this valve is designed as a one-way valve. The board further notes that even if, as submitted by the respondent, check valve 110 was designed as a one-way valve, D15 does not disclose that it is sealingly coupled to the inlet of the pump.
- 14.7.5 The third valve disclosed in D15 - the "*solenoid valve 118*" - is present in an embodiment with an intermittent pump, and located between and communicating with the negative wound pressure dressing and the pump. It can, once the intermittent pump has reached the desired pressure, open and allow atmospheric air into the

negative wound pressure dressing (see paragraph [0039] and figure 4). Document D15 does not disclose that this valve is designed as a one-way valve.

- 14.8 Document D15 does therefore not disclose a pump assembly comprising a one-way flow valve according to claim 1 of the main request.
- 14.9 The respondent argued that document D15 disclosed that the pump assembly has been sterilized, and that at least an inside and an outside of the housing has been sterilized. The respondent in particular submitted, by reference to paragraph [0004] of D15, that sterilization was a standard measure in the respective industry, and that claim 1 of the main request did not require the device to be repeatedly sterilized.
- 14.10 The board comes to the conclusion that there is no disclosure in document D15 that the pump assembly has been sterilized such that at least an inside and an outside of the housing, the flow pathway, the first and second valves, and the pump have been sterilized.
- 14.11 Although paragraph [0004] of D15 discloses that, for some of the available negative pressure wound therapy systems, the whole system must be sent for sterilization, this passage does not disclose that this is the case for the system disclosed in D15, in particular not for a system in accordance with figures 1 and 4. Furthermore, paragraph [0043] of document D15 discloses that *"... the control unit 200 (of the disclosed device) would not need aggressive sterilization when utilized with another patient."* Sterilization of the pump assembly is thus not disclosed in D15.

15. The board thus comes to the conclusion that the subject-matter of claim 1 of the main request is novel in view of document D15 (Article 54 EPC).

*Inventive step (Article 56 EPC)*

16. The opposition division considered the disclosure of document D15 to be the closest prior art. Two differing features were identified, *i.e.* "... a second valve configured to control a flow of a fluid through the outlet ..." and "... wherein the pump assembly has been sterilized such that at least an inside (...) of the housing (...) have been sterilized". The opposition division concluded that these features did not provide any synergetic effect, and that the two independent technical problems resulting therefrom were solved in an obvious manner considering the additional technical teaching of documents D16 or D2/D2a (for a first problem of providing an alternative pumping technique), and D21 (for a second problem of providing a device that could further avoid contamination of the surroundings).
17. The appellant contested the opposition division's conclusion. In particular, the appellant submitted that additional differing features distinguished the claimed pump assembly from the disclosure of D15 (see point 13. of this decision), and that the opposition division did erroneously apply the partial problems approach, although the distinguishing features acted together to solve a common technical problem, *i.e.* sterilization of the internal and external components of the pump assembly. In addition, even if the problems were defined according to the impugned decision, the solutions according to claim 1 of the main request were based on an inventive step. The appellant did not

consider documents D16 or D2/D2a to provide a solution to the problem of providing an alternative pumping technique, and did not consider document D21 to provide a solution to the problem of providing a device that could further avoid contamination of the surroundings. The appellant argued that the technical teachings provided in these documents were not compatible with the pump assembly as disclosed in D15, at least not without additional modification thereof.

18. The respondent essentially argued lack of inventive step following the reasoning of the opposition division.

19. The board comes to the following conclusions:

*The contested patent*

19.1 The patent relates to apparatuses for dressing and treating a wound with topical negative pressure therapy, in particular to a pump assembly for reduced pressure therapy (see paragraphs [0001] and [0004]). In the description of the patent in suit, the problem of sterilizing pump assemblies is highlighted (see paragraphs [0032], [0062] and [0077]). In order to improve sterilization, pump assemblies according to claim 1 are provided. According to the submissions of the appellant, the particular arrangement and types of valves allowed for improved sterilization of the inside as well as the outside of the pump assembly by sterilizing gas.

*The closest prior art - document D15*

19.2 The parties concurred with the opposition division that document D15 represents the closest prior art. The

board sees no reason to differ. The document discloses devices with a pump for providing negative pressure for a wound therapy device (see paragraph [0002]).

*The differing features*

- 19.3 As already stated above, the pump assembly according to claim 1 of the main request differs from the pump assembly disclosed in D15 in that it comprises a one-way flow valve, in particular a one-way flow valve supported within a manifold, and in that the pump assembly has been sterilized (see points 14.8 and 14.10 of this decision).

*The technical problem*

- 19.4 According to the appellant, the position and type of valves allowed for the inside, the outside, and the flow pathway in particular between the first and the second valves of the pump and the pump assembly to be sterilized by sterilizing gas. The appellant submitted that the use of a one-way valve (246, 1030), sealingly coupled to the inlet of the pump, and configured to substantially prevent a flow of gas through the flow pathway in a direction of flow away from the pump, allowed the application of sterilizing gas via the outlet (252) of the pump, without the gas leaving the assembly through the one-way valve, in order to build up sufficient pressure of sterilizing gas within the flow pathway, in particular within the flow pathway of the pump, such as the area between the one-way valve and the inlet valve of the pump, and irrespective of introducing the sterilization gas via pump outlet (252) or via the one-way flow valve (246). The appellant further argued, by reference to paragraph [0077] of the patent in suit, that it was the arrangement of valves

and the use of the one-way flow valve which allowed for efficient sterilization.

- 19.5 The respondent argued that the technical problem was merely to find an alternative position for the one-way valve, since document D15 already disclosed a one-way valve 110.
- 19.6 The respondent's submission is not convincing. Document D15 does not disclose a one-way valve (see point 14.8 of this decision). The technical problem can thus not be seen in the provision of a pump assembly with an alternative position for such a valve. Furthermore, even if, as submitted by the respondent, check valve 110 of D15 was in the form of a one-way valve, it would not operate as the one-way valve (246) according to claim 1 of the main request does. According to paragraph [0037] of D15, the check valve prevents flow of positive pressure from the pump module to the dressing. Since the dressing is connected to the pump via quick release valve 18, tubing 16 and port 14 - but not via check valve 110, release of positive pressure occurs by opening check valve 110. In contrast, one-way flow valve (246, 1030) according to claim 1 of the main request is configured to substantially prevent a flow of gas through the flow pathway in a direction of flow away from the pump. The valve thus remains closed in case of increased pressure. It thus allows build-up of sterilizing gas pressure between the one-way valve and the pump.
- 19.7 The board is also convinced that the technical effect relied upon by the appellant can be achieved by the differing features.

19.8 The technical problem can thus be seen in the provision of a pump assembly allowing for efficient gas sterilization of the inside and outside of the pump assembly components, *i.e.* the housing, the flow pathway, the first and second valves, and the pump.

*Solution to the technical problem*

19.9 According to claim 1 of the main request, the technical problem is solved by the provision of a pump assembly wherein "*... a one-way flow valve (246, 1030) is in fluid communication with the pump and supported within a manifold (240) that is disposed in the housing and sealingly coupled to the inlet of the pump, the one-way flow valve being configured to substantially prevent a flow of gas through the flow pathway in a direction of flow away from the pump ...*".

*Non-obviousness of the claimed solution*

19.10 Document D15 does not disclose that the pump assembly be sterilized to re-use. According to paragraph [0010] of the document, part of the device is disposed of. There is thus no incentive for the skilled person to adapt the pump assembly disclosed in document D15 in order to provide an assembly according to claim 1 of the main request. Even if, as argued by the respondent, one-way valves were known in the field, the respondent could not refer to a particular teaching directing the skilled person to the specific location of the one-way valve according to claim 1 of the main request.

20. The main request thus meets the requirements of Article 56 EPC.

21. Since, for the reasons above, the main request is allowable, there is no need to consider the auxiliary requests.

## Order

### For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the opposition division with the order to maintain the patent on the basis of the claims of the main request and a description to be adapted.

The Registrar:

The Chairman:



C. Rodríguez Rodríguez

P. Gryczka

Decision electronically authenticated