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**D E C I S I O N**  
**of 16 May 2002**

**Case Number:** T 0618/99 - 3.3.5

**Application Number:** 92109644.2

**Publication Number:** 0518250

**IPC:** B01D 29/11

**Language of the proceedings:** EN

**Title of invention:**

Method and apparatus for testing the integrity of filter elements

**Patentee:**

PALL CORPORATION

**Opponent:**

Sartorius AG

**Headword:**

Testing filters/PALL

**Relevant legal provisions:**

EPC Art. 100(b)

**Keyword:**

"Sufficiency of disclosure - yes (after amendment)"

**Decisions cited:**

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**Catchword:**

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Case Number: T 0618/99 - 3.3.5

**D E C I S I O N**  
**of the Technical Board of Appeal 3.3.5**  
**of 16 May 2002**

**Appellant:** PALL CORPORATION  
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**Representative:** Geissler, Bernhard, Dr. jur., Dipl.-Phys.  
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**Respondent:** Sartorius AG  
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**Representative:** Rucker, Ernst, Dr. Dipl.-Chem.  
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**Decision under appeal:** Decision of the Opposition Division of the  
European Patent Office posted 25 March 1999  
revoking European patent No. 0 518 250 pursuant  
to Article 102(1) EPC.

**Composition of the Board:**

**Chairman:** R. K. Spangenberg  
**Members:** G. J. Wassenaar  
M. B. Günzel

## Summary of Facts and Submissions

I. The appeal is from the decision of the Opposition Division to revoke European patent No. 0 518 250, which was granted in response to European patent application No. 92 109 644.2.

Claim 1 as granted read as follows:

"A method of testing the integrity of filter elements in a filter assembly comprising a plurality of filter elements which are sub-divided into a plurality of sections each containing filter elements said method comprising the steps:

a) wetting the filter material of said plurality of filter elements,

b) subjecting the filter elements with wetted filter material to a gas pressure,

c) measuring the bulk gas flow rate through the wetted filter material of all of said plurality of filter elements,

d) determining whether the measured flow rate deviates from a first desired flow rate by an amount within a first preset range, wherein a deviation within said preset range indicates that all filter elements are intact, and if the measured bulk gas flow rate exceeds said first desired flow rate by an amount greater than allowed by said first preset range,

e) closing the gas passage through at least one section of filter elements containing a portion of said

plurality of filter elements,

f) measuring the bulk gas flow rate through the wetted filter material of the remaining filter elements, and

g) determining whether the measured flow rate of step f) deviates from a second desired flow rate corresponding to the resulting reduced number of filter elements by an amount within a second preset range,

wherein a deviation within said second preset range indicates that one or more of the filter elements in said at least one section of step e) is not intact, and if the measured bulk gas flow rate of step f) exceeds said second desired flow rate by a amount greater than allowed by said second preset rage, the steps e), f) and g) are repeated while closing the gas passage in step e) for other sections of said plurality of filter elements until a deviation is found in step g) indicating a single section of filter elements in which at least one filter element is not intact."

- II. The only opposition ground was insufficient disclosure (Article 100(b) EPC). The Opposition Division held that a skilled person could not, without undue burden, determine important parameters of the process according to claim 1, and that the patent did not clearly disclose how to solve the problem underlying the invention stated therein, ie to reliably detect a defective filter element from a plurality of filter elements in a systematic and efficient manner. The examples provided by the opponent showed that with the claimed process it was in general not possible to detect whether a filter would still function properly.

III. In the statement of the grounds of appeal, the appellant argued that for the issue of insufficiency the burden of proof was on the side of the respondent, and that the respondent's example calculations were not correct and not based on realistic assumptions. It was further argued that at least in a situation where a deficient filter caused a significant increase in flow rate the skilled person could easily determine the required preset range. The example representing real life conditions in a brewery, presented during oral proceedings before the Opposition Division (Example 2, Annex III of the contested decision), showed that it was possible to detect a deficient filter element out of 392 filter elements.

IV. The respondent maintained the objections under Article 100(b) EPC and argued that in the patent specification the features "first and second desired flow rate" and "first and second preset range" were not defined. By taking realistic assumptions for these features it was not possible to find deficient filters in a reliable and simple way. In the pharmaceutical and beverage industry it must be excluded that a single defective filter remained undetected and that a single bacterium could pass the filter barrier. The examples provided by the respondent were based on daily practice in the respondent's firm and showed that with the process according to the patent in suit it could not be excluded that a deficient filter remained undetected.

V. During oral proceedings, which took place on 16 May 2002, where the respondent, as announced by the letter dated 19 November 2001, was not represented, the appellant submitted a new set of claims as its main request.

Claim 1 thereof was based on claim 5 as granted and its introductory part read as follows; the rest of the claim being worded as granted:

"A method of testing the integrity of filter elements in a filter assembly comprising a plurality of filter elements which are sub-divided into a plurality of sections each containing filter elements, wherein said filter elements have been subjected to a sterilization at high temperatures prior to said integrity testing, said method comprising the steps:"

With respect to this claim the appellant argued that membrane filters used in the pharmaceutical and beverage industry had to be sterilized before use. This was generally done by hot water or steam under pressure, which might rupture the membrane. Deficiencies caused by sterilization therefore always resulted in a flow rate increase of at least one order of magnitude, which could be easily detected by the process according to claim 1. It was admitted that small deviations of the desired flow rate due to wear during use could not be detected in this way, but that this was not a real problem because in normal use the properties of the filter material did not change suddenly. It was only during the sterilization step between subsequent filtration processes that the filter material could be deteriorated.

VI. The appellant (patentee) requested that the decision under appeal be set aside and that the patent be maintained with the claims of the main request filed during the oral proceedings.

The respondent (opponent) requested in writing that the

appeal be dismissed.

### **Reasons for the Decision**

1. The appeal is admissible.
2. The scope of present claim 1 is identical to that of claim 5 as granted. The amendment, therefore does not broaden the scope of protection so that no objections under Article 123(3) EPC arise. Since the granted claims were not attacked under Article 100(c) EPC during the opposition proceedings, the Board has no power to investigate whether the amendments also fulfil the requirements of Article 123(2) EPC.
3. Claim 1 relates to the testing of filter elements in a filter assembly comprising wetttable filter material, which must be sterilized before use. This implies that the filter assembly is for use in processes where it is necessary to sterilize the filter material and where the pores of the filter material should be small enough to separate bacteria or other microorganisms. Filter elements comprising such filter material are used in the pharmaceutical and beverage industry. Because of the small pores the filter material has a high resistance to pressurized air so that even a relatively small hole, slit or crack dramatically increases the flow rate of the air if it is tested with pressurized air. According to the patent specification a high temperature sterilization procedure can deteriorate the integrity of the filter material especially if the material structure is altered by repeated sterilization (column 1, lines 17 to 29 and column 4, lines 12 to 27). It is thus credible that deterioration of the

filter material by high temperature sterilization may result in an increase of the flow rate of at least one order of magnitude when the filter is tested with pressurized air.

4. The examples given by the respondent show that if the preset range for the filter assembly is taken to be of the same order of magnitude as the desired flow rate for an individual filter, defective filters no longer fulfilling the flow rate specifications of the filter material, cannot reliably be detected by the process according to granted claim 1. Since this is no longer contested by the appellant, there is no need to discuss these examples in more detail. The respondent has not provided evidence and has, in fact, never argued that the method of claim 1 as granted was not suitable to detect a filter element having a major defect due to high temperature sterilization, resulting in an flow rate increase of an order of magnitude higher than that of the intact individual filter element. To detect such major defects a preset range can be taken which is also an order of magnitude higher than the desired flow rate of an individual filter element but lower than the increase of the flow rate caused by the defect (see the example according to Annex III of the contested decision). It is evident that the choice of the preset range is dependent upon the type of filter assembly, the amount of filters in the assembly and the standard deviation of the flow rate for a properly functioning filter assembly. For the detection of major defects, as is the object of the invention as now defined, the choice of the preset range is not very critical and the skilled person will immediately recognize that it generally should exceed the established flow rate of the intact filter membranes by only a small amount (see



the appellant's letter dated 29 November 2000). The Board, therefore, holds that it is no undue burden for the skilled person to find out the suitable preset range for detecting the kind of defects which may be caused by the sterilization treatment.

5. It can of course not be excluded that during use and subsequent sterilization occasionally also minor defects in the filter elements may occur, which do not dramatically increase the flow rate but result in an increase of the flow rate of the same order of magnitude as the flow rate through an individual filter element. From the uncontested fact, that with the method of the invention it is impossible to detect such defects, it cannot be derived that the invention cannot be applied over the whole range of the claim. Subject-matter falling under the terms of a claim only on a literal, purely linguistic construction but which evidently cannot be performed because of theoretical or practical limitations well known to a person skilled in the art, to which the claim is addressed, cannot be regarded as forming part of the invention. In the present case, the Board is satisfied that the skilled person will be aware of the limits of the method of present claim 1 but will have no problem to perform the invention for the purpose for which it has been developed, ie the detection of a deteriorated filter in a filter assembly after a sterilization treatment in an efficient and reliable way, without the need for testing each filter element separately.
6. For these reasons the Board holds that the invention as now claimed, interpreted in a meaningful way, can be performed by a person skilled in the art without undue burden. Thus the ground of opposition under

Article 100(b) EPC does not prejudice the maintenance of the patent with the amended claims. Since this has been the only ground of opposition, the Board has no power to consider novelty and inventive step of the subject matter of the present claims.

7. The respondent was not represented during the oral proceedings and could thus not react to the amendments submitted therein. A limitation of the independent claim to the subject-matter of a granted dependent claim is, however, a normal defence against objections raised by an opponent, which cannot be regarded as a surprising change of the subject-matter of the appeal proceedings. The respondent was duly summoned to the oral proceedings and had, therefore, the opportunity to present his comments as provided by Article 113(1) EPC. By deliberately not attending the oral proceedings he deprived himself willingly of the opportunity to produce further comments.

## **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 with the claims of the main request filed in the oral proceedings before the Board and a description to be adapted.

The Registrar:

The Chairman:

P. Martorana

R. Spangenberg