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**Datasheet for the decision  
of 14 March 2011**

**Case Number:** T 2362/08 - 3.3.07

**Application Number:** 97944406.4

**Publication Number:** 0877648

**IPC:** B01D 65/02

**Language of the proceedings:** EN

**Title of invention:**

System for filtering medical and biological fluids

**Patent Proprietors:**

Baxter International Inc.

**Opponents:**

Bayer Technology Services GmbH

**Headword:**

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**Relevant legal provisions:**

EPC Art. 113(1), 114(1)

EPC R. 103(1)(a), 116

RPBA Art. 11

**Relevant legal provisions (EPC 1973):**

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**Keyword:**

"Basis of decision - right to be heard (no)"

"Substantial procedural violation (yes)"

"Decision re-appeals - remittal (yes)"

**Decisions cited:**

G 0010/91

**Catchword:**

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Case Number: T 2362/08 - 3.3.07

**D E C I S I O N**  
of the Technical Board of Appeal 3.3.07  
of 14 March 2011

**Appellants:**  
(Patent Proprietors) Baxter International Inc.  
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**Respondents:**  
(Opponents) Bayer Technology Services GmbH  
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**Representative:** Nohr, Guido  
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**Decision under appeal:** Decision of the Opposition Division of the  
European Patent Office posted 5 December 2008  
revoking European patent No. 0877648 pursuant  
to Article 101(2) and (3)(b) EPC.

**Composition of the Board:**

**Chairman:** J. Riolo  
**Members:** D. Semino  
M.-B. Tardo-Dino

## Summary of Facts and Submissions

- I. The appeal of the patent proprietors (appellants) lies from the decision of the opposition division to revoke European Patent No. 0 877 648 announced on 7 November 2008.
  
- II. Granted claim 1 was directed to a method for separating a suspension comprising at least first and second types of particles of different shape, the first type of particles being either deformable at a relatively lower force than the second type of particles or deformable at a relatively faster rate than the second type of particles, the separation being accomplished by means of a filter membrane having pores with precisely dimensioned shapes and sizes, in a predefined geometric pattern of pores of precise and consistent size, shape and relative spacing to one another. Independent claim 14 was directed to an apparatus for separating such a suspension.
  
- III. A notice of opposition was filed against the granted patent requesting revocation of the patent in its entirety on the grounds of Article 100(a) EPC (lack of novelty and lack of an inventive step), Article 100(b) EPC (insufficient disclosure) and Article 100(c) EPC (added subject-matter).

With regard to the substantiation of the objection relating to insufficiency of disclosure, two lines of argument were followed by the opponents in their notice of opposition. According to the first line, it was objected that granted claims 1 and 14 did not contain any reference to the many process parameters listed in

paragraph [0041] of the patent as interrelated parameters which must be considered in membrane dimension optimisation. As to the second line of argument, it was submitted that no definition of the term "precise", which was used in the claims with reference to the size and shape of the membrane pores, appeared in the patent.

IV. In their reply to the notice of opposition the patent proprietors countered *inter alia* the objection of insufficiency of disclosure by pointing out that the opponents had not substantiated their allegation with any verifiable facts or evidence, that paragraph [0041] of the patent did not refer to the basic act of putting the invention into practice, but to the optional and additional step of improving its implementation ("membrane dimension optimisation"), and that the second line of argument had nothing to do with the sufficiency issue, but was a disguised attempt to argue lack of clarity.

V. In the summons to oral proceedings a final date for making written submissions and/or amendments according to Rule 116 EPC was set. In the communication accompanying the summons, the opposition division expressed *inter alia* their preliminary opinion with regard to sufficiency of disclosure as follows:

"The opposition division cannot at present subscribe to the opponent's point of view that the patent in suit does not sufficiently disclose the invention. This is because the description contains detailed information about the membranes to be used, the conditions during the filtration and the type of liquid to be filtered

(see paragraphs [0032]-[0040]). The passage on paragraph [0041] referred to by the opponent does not appear to be related to the invention as defined by claims 1 and 14 but merely to provide suggestions for further optimization of the membranes used in the present invention. Finally, the opposition division would like to point out that the burden of proof is upon the opponent to establish that the skilled person would be unable to carry out the invention after reading the patent in suit (case law of the boards of appeal, e.g. the decision T 182/89, OJ 1991, 391). It is noted that no experimental evidence has been submitted by the opponent to that effect."

- VI. In preparation for the oral proceedings the patent proprietors filed first to third auxiliary requests and four documents, namely a declaration by an expert and Exhibits 1 to 3.
  
- VII. During the oral proceedings before the opposition division compliance of the patent as granted with the requirement of sufficiency of disclosure was one topic of discussion.

According to the minutes of the oral proceedings both parties presented their arguments, the opposition division drew attention to some points raised by Exhibit 3, the patent proprietors indicated that the burden of proof for lack of disclosure was on the opponents and a discussion on the case law on sufficiency took place (Point 9 of the minutes). In addition, the relevance of prior art document D3 (WO-A-95/13860, cited in the notice of opposition) and the background knowledge of the skilled person were

discussed, after which the opposition division came to the conclusion that the patent as granted did not comply with the requirements of Article 83 EPC (Points 10 and 13 of the minutes).

Sufficiency of disclosure was also discussed for the first to third auxiliary requests, which were also found not to meet the requirements of Article 83 EPC (Points 15 to 17 of the minutes).

The opposition division then used its discretion not to admit a fourth auxiliary request (Point 18 of the minutes), which was the first of three further auxiliary requests filed during oral proceedings immediately after the finding on the insufficiency of the granted patent (Point 14 of the minutes) and in which the first and second types of particles had been limited to "animal cells".

VIII. As far as relevant to the present decision, the decision of the opposition division can be summarised as follows:

- (a) Granted claim 1 limited the particles to be separated only in that they should differ from each other in shape and deformability and the membranes only in that they should have pores with precisely dimensioned shapes and sizes, in a predefined geometric pattern of pores of precise and consistent size, shape and relative spacing to one another. In spite of that, the description provided only guidance for the separation of blood cells, indicated very broad ranges for the membrane dimensions unless they referred to the

specific separation of blood cells, and provided extremely vague indications concerning the process conditions even for the preferred separation of blood cells.

- (b) For the filtration of a generic type of suspension the skilled person would need to investigate the characteristics of the particles to be separated, to select a suitable membrane and to determine the mode of operation and the process conditions. Since the patent specification did not contain a theoretical model or scientific explanation which would allow for accurate predictions, that work would have to be conducted experimentally and would amount to an extensive research programme which could not be accomplished without undue burden. This was confirmed by the declaration of the expert filed by the patent proprietors in preparation for the oral proceedings, in which he expressed scepticism about the possibility of separating particles unless they differed strongly in size, and was further confirmed by the lack of information in the patent about how to choose the membranes and the process conditions which had been shown to work in Exhibit 3.
- (c) While the onus was generally on the opponents to prove a lack of disclosure and the opponents did not provide evidence in this respect, in the present case it was possible to form an opinion on the basis of the evidence on file and of the information contained in the patent in suit. This was justified by the lack of concrete information in the patent, e.g. in the form of working



examples, which made it extremely difficult, if not impossible, for the opponents to prove conclusively that the invention did not work for the whole range claimed. Consequently it was concluded that the granted patent did not disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.

(d) The amendments in claims 1 and 14 according to the first to third auxiliary requests did not change the situation with regard to sufficiency.

(e) The limitation of the particles to animal cells in the fourth auxiliary request was based on a passage in the description and could not have been easily foreseen by the opponents, who at a late stage of the procedure could usually expect amendments to come in the form of a combination of claims as granted, so that the request was "not admissible pursuant to Article 116(2) EPC (*sic*)".

IX. The patent proprietors (appellants) filed a notice of appeal against the above decision. In the statement setting out the grounds of appeal they complained that substantial procedural violations occurred during the opposition proceedings and requested a remittal to the opposition division in the event that the Board were unable to come to a decision to reject the opposition. In addition they submitted nine sets of claims as first to ninth auxiliary requests.

X. In a communication sent in preparation for the oral proceedings the Board expressed the provisional opinion

that substantial procedural violations occurred during the opposition proceedings, especially with respect to the right to be heard, so that the patent proprietors had not been able to enjoy a fair trial, and indicated that the scheduled oral proceedings would be limited to the discussion of that point.

XI. Oral proceedings took place before the Board on 14 March 2011.

XII. The arguments of the appellants (patent proprietors), as far as relevant to the present decision, can be summarised as follows:

- (a) The issue of lack of sufficiency of disclosure was not properly substantiated in the notice of opposition. The two points raised there related to the requirements of Article 84 EPC (lack of essential features and presence of an unclear term in the claims) and were not followed up by the opposition division.
- (b) The objection of lack of sufficiency as addressed in the decision was a completely new issue which was raised for the first time at the oral proceedings before the opposition division and for which the patent proprietors had no proper opportunity to respond. While in the communication accompanying the invitation to oral proceedings the opposition division had correctly placed the burden of proof regarding lack of sufficiency on the opponents, who did not file any evidence, the burden of proof was shifted during the oral proceedings to the wrong party and the conclusion

of the opposition division was not based on verifiable facts. In view of that the patent proprietors did not enjoy a fair hearing by the opposition division.

- (c) The fourth auxiliary request contained amendments which were a genuine attempt to overcome the newly raised objections and was filed as soon as those objections were known. In view of this it could not be considered as late filed, no discretion could be exercised by the opposition division and the request had to be admitted on the grounds that the subject of the proceedings had changed. Without an opportunity to overcome the newly raised objections, the patent proprietors' right to be heard had not been respected.
- (d) In view of those substantial procedural violations, the patent proprietors had not enjoyed a fair hearing by the opposition division, so that not only the request for remittal, but also that for a change of the composition of the opposition division was justified. Moreover, in view of the length of the proceedings, accelerated treatment of the case by the opposition division was appropriate.

XIII. The arguments of the respondents (opponents), as far as relevant to the present decision, can be summarised as follows:

- (a) Lack of sufficiency over the whole breadth of the granted claims had already been raised and substantiated in the notice of opposition. The

points raised there could be considered as relevant both to Article 84 and to Article 83 EPC due to the overlap between their requirements. The statements of the opposition division in the communication accompanying the invitation to oral proceedings were only a preliminary non-binding opinion and could be overturned in the decision of the opposition division without it committing any procedural violation. All documents used by the opposition division to justify its decision had already been filed before the oral proceedings took place, all relevant arguments had already been presented and the patent proprietors were given enough time during the oral proceedings to address the issue and be heard by the opposition division.

(b) It was within the discretion of the opposition division to decide on the admissibility of the fourth auxiliary request and the exercise of this discretion could not lead to a procedural violation.

(c) For these reasons, remittal of the case to the opposition division was not justified.

XIV. The appellants (patent proprietors) requested that the decision under appeal be set aside and the patent be maintained as granted or alternatively on the basis of one of the nine auxiliary requests filed with the statement setting out the grounds of appeal. In the event that the Board did not accept one of their above-mentioned requests, they requested remittal to the opposition division in a different composition, for

substantial procedural violations, and reimbursement of the appeal fee. They further requested accelerated proceedings before the opposition division.

- XV. The respondents (opponents) requested that the appeal be dismissed.

### **Reasons for the Decision**

1. The appeal is admissible.

#### *Substantial procedural violations*

2. *Decision on sufficiency of disclosure*

- 2.1 While the ground of insufficiency of disclosure appeared in the notice of opposition, the arguments in the notice were only based on the lack of any reference in the granted claims to the parameters in paragraph [0041] of the patent and on the lack of a definition for the term "precise". No further submission on insufficiency was filed by the opponents in writing and, before the oral proceedings took place, no further issue was raised by the opposition division, which in the communication accompanying the invitation to oral proceedings did not agree with the objections of the opponents, placed the burden of proof on them to establish that the skilled person would be unable to carry out the invention after reading the patent in suit and noted that the opponents had not submitted any experimental evidence.

2.2 In its decision on insufficiency of disclosure the opposition division did not follow up the points raised in the notice of opposition, but developed a completely different line of argument, which did not emerge before the oral proceedings and was based on the breadth of the independent claims, on the guidance given in the description only for the separation of blood cells, on the extensive experimental work which would be necessary to put the invention into practice over the whole breadth and on the doubts raised by some of the submissions of the patent proprietors filed in preparation for the oral proceedings.

2.3 An opposition division may in application of Article 114(1) EPC consider grounds for opposition which have not been properly submitted and substantiated if they would seem *prima facie* to prejudice in whole or in part the maintenance of the European patent (G 10/91, OJ EPO 1993, 420). Consequently, in analysing whether the opposition division committed a substantial procedural violation in the case in hand, it is not relevant to consider whether, as submitted by the patent proprietors, the ground of insufficient disclosure was properly substantiated in the notice of opposition. This is a matter of admissibility, which is not relevant for the question of the right to be heard arising in the present case.

2.4 Thus, what needs to be determined is whether the patent proprietors' right to be heard according to Article 113(1) EPC has been safeguarded, i.e. whether the decision is based on grounds or evidence on which the patent proprietors had an opportunity to present

their comments. In order for this condition to be fulfilled it is not sufficient that the patent proprietors were formally informed of the ground of opposition. Rather, they must also have been made aware of the facts and evidence which were intended to substantiate this ground and could lead to a finding of invalidity and revocation of the patent and must furthermore have been given a proper opportunity to present comments in reply to the ground and its substantiation (see Case Law of the Boards of Appeal, 6th Edition 2010, VII.D.5.2.5 a)). In other words, in order for the requirements of Article 113(1) EPC to be fulfilled, the facts on which the opposition division intended to base its decision should have been clearly identified in order to define the legal and factual framework of the case, so that the patent proprietors might foresee the possible attacks and prepare their defence accordingly.

- 2.5 In the present case, not only was the discussion during the oral proceedings directed to a completely new approach in respect of the issue of insufficiency of disclosure, but the patent proprietors had to face an unexpected reversal of opinion from the opposition division (see paragraphs V, VII, VIII, 2.2 above). Indeed, in its preliminary opinion, the opposition division informed the patent proprietors that the burden of proof rested on the opponents, who by deciding not to file any evidence had not discharged it, while according to the new analysis pursued in the decision the opponents were discharged of the burden of proof without providing any evidence.

2.6 In the present circumstances, in which a completely new line of argument on a substantive issue (insufficiency of disclosure) was raised for the first time at the oral proceedings and in which during the oral proceedings the opposition division unexpectedly reversed its previously expressed opinion and thereby shifted the burden of proof to the patent proprietors, the Board considers that the simple formal hearing of the patent proprietors on the issue at the oral proceedings cannot be considered to have been a proper opportunity for the patent proprietors to present their comments.

2.7 By presenting the new legal and factual framework only at the oral proceedings and by coming to a final decision on the issue without first having given the patent proprietors a proper opportunity to respond, the opposition division did not respect their right to be heard and committed a procedural violation. This course of action led to the invalidity of all the requests filed by the patent proprietors before the oral proceedings and maintained by them at the start of the oral proceedings. Therefore a causal link exists between the non-respect of the right to be heard and the decision made. Consequently the procedural violation was a substantial one.

3. *Admissibility of the fourth auxiliary request*

3.1 Immediately after the opposition division announced at the oral proceedings its finding on the insufficiency of disclosure of the patent as granted, the patent proprietors filed three auxiliary requests, the first of which (fourth auxiliary request) limited the



particles to be separated to "animal cells". There could be no doubt that such an amendment was introduced in order to address the new line of argument on insufficiency of disclosure according to which the patent in suit contained no guidance for the separation of all possible kinds of particles of different shape and deformability, but did provide some guidance for the separation of blood cells (a specific kind of animal cells).

- 3.2 The opposition division decided to exercise its discretion and not admit the fourth auxiliary request, presumably according to Rule 116(2) EPC (Article 116(2) EPC was erroneously cited) on the ground that the limitation to animal cells only appeared in the description and that at a late stage of the procedure the opponents could usually expect amendments to come in the form of a combination of claims as granted.
- 3.3 Rule 116(2) EPC in combination with Rule 116(1) EPC prescribes that, if the patent proprietors have been notified of the grounds prejudicing the maintenance of the patent, they may be invited to submit, by a specific date, documents which meet the requirements of the EPC and that documents presented after that date need not be considered, unless admitted on the grounds that the subject of the proceedings has changed. The invitation according to Rule 116(2) EPC was present in the summons and a specific date was set.
- 3.4 However, the conditions foreseen in Rule 116(2) EPC do not apply to the present case. The patent proprietors were not notified of the grounds relating to insufficiency of disclosure on which maintenance of the

patent was prejudiced (see paragraphs 2.1 to 2.7 above) and had no reason to file amended claims to take into account reasons which were still unknown to them. Moreover, the subject of the proceedings changed during the oral proceedings in view of the completely new line of argument on sufficiency of disclosure which led the opposition division to find the patent invalid both in the granted version and according to the auxiliary requests filed in preparation for the oral proceedings. Under such circumstances the opposition division was not in a position to exercise discretion with respect to the admissibility of the fourth auxiliary request on the basis of Rule 116(1) EPC.

- 3.5 It is fundamental to the principle of the right to be heard (Article 113(1) EPC) and in accordance with the principle of a fair hearing that the patent proprietors, when confronted with new objections, should be given not only the opportunity to present their comments, but also the opportunities to react thereto by amending the claims in order to overcome the objections. If the opposition division was of the opinion that the opponents could not be prepared to discuss the request filed in reaction to the new objections on the very day of the oral proceedings, they should have adjourned the proceedings, but could not consider the request as late filed and decide not to admit it. This conclusion is not altered by the fact that further, lower ranking requests of the patent proprietors (fifth and sixth auxiliary requests) were admitted.

3.6 For these reasons, by deciding not to admit the fourth auxiliary request the opposition division did not respect a fundamental right of the patent proprietors and committed a further substantial procedural violation.

4. *Remittal*

4.1 The most important factor to be considered in deciding the further course of the proceedings is that the patent proprietors did not receive a fair hearing before the first instance in relation to the ground of insufficiency of disclosure prior to the issue of a decision on this ground. Because of this the patent proprietors had to proceed to appeal in order to defend fairly the sufficiency of disclosure of the patent. This means that the procedure on this ground was effectively reduced to a single instance.

4.2 On this basis, it follows that the decision of the opposition division is to be set aside. Moreover, in order for the patent proprietors not to be deprived of the possibility of arguing the case at two levels of jurisdiction, the Board considers it appropriate to exercise its power under Article 111(1) EPC and remit the case to the first instance for further prosecution without proceeding to analyse the decision in its substantive aspects and decide on the requests of the patent proprietors on file.

4.3 The Board has no reason to suspect partiality on the part of the members of the opposition division during the conduct of the proceedings, or to assume that they would necessarily be partial or prejudiced if they

reheard the case. However, after substantial procedural irregularities in the first proceedings, it is fundamental that the parties have no ground to suspect in the further proceedings that they have not received a fair hearing, as they might well do if the same opposition division were again to revoke the patent even after conducting the proceedings in an impeccable way.

4.4 For these reasons, the Board considers a change of composition of the opposition division (i.e. a composition with three new members) as appropriate to avoid any possible suspicion or ground of dissatisfaction. It is felt that such a decision is also fairer to the members of the opposition division having taken the decision under appeal, who would otherwise need to attempt to put out of their minds the result of their previous decision before hearing and deciding on the case a second time.

5. *Reimbursement of the appeal fee*

5.1 In view of the foregoing, the appeal is successful to the extent that the decision under appeal is set aside. Moreover, as a consequence of the substantial procedural violations the patent proprietors were only able to have their right to be heard restored by filing the appeal. In view of this the Board considers the reimbursement of the appeal fee as equitable by reason of a substantial procedural violation and the conditions for such a reimbursement under Rule 103(1)(a) EPC as met.

6. *Accelerated opposition proceedings*

6.1 There is no provision of the EPC under which any competence is given to a Board of Appeal to decide the time frame of first instance proceedings after remittal. The Board therefore cannot take any decision on the request for acceleration of the opposition proceedings. This should be presented to the opposition division taking into account the conditions under which a request of this kind may be made (see notice in OJ EPO 2008, 221).

**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 in a different composition.
3. The appeal fee is reimbursed.

The Registrar

The Chairman

S. Fabiani

J. Riolo