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**Datasheet for the decision
of 20 May 2015**

Case Number: T 2016/11 - 3.3.01

Application Number: 01952563.3

Publication Number: 1312008

IPC: A61M25/00

Language of the proceedings: EN

Title of invention:

APPARATUS AND KITS FOR LOCKING AND DISINFECTING IMPLANTED
CATHETERS

Patent Proprietor:

Excelsior Medical Corporation

Opponent:

Strehlke, Ingo K.

Headword:

Antimicrobial and anticoagulant locking compositions/EXCELSIOR

Relevant legal provisions:

EPC Art. 54, 123(2), 111(1)

RPBA Art. 12

Keyword:

Admission of requests (yes)

Admission of late filed documents: discretion correctly exercised

Main request, first to third auxiliary requests: novelty - (no)

Fourth auxiliary request: Amendments -
intermediate generalisation

Remittal to the department of first instance (no)

Decisions cited:

R 0016/09, T 1067/97, T 0553/02, T 0764/06, T 0784/06,

T 1537/07, T 0611/09

Catchword:



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Case Number: T 2016/11 - 3.3.01

D E C I S I O N
of Technical Board of Appeal 3.3.01
of 20 May 2015

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Decision under appeal: **Interlocutory decision of the Opposition
Division of the European Patent Office posted on
11 July 2011 concerning maintenance of the
European Patent No. 1312008 in amended form.**

Composition of the Board:

Chairman A. Lindner
Members: G. Seufert
D. Rogers

Summary of Facts and Submissions

- I. Appellant 1 (opponent) and appellant 2 (patent proprietor) lodged an appeal against the interlocutory decision of the opposition division on the amended form in which the European patent No. 1 312 008 could be maintained.
- II. The present decision refers to the following documents:
- (5) US 4,929,242
 - (6) US 5,077,281
 - (8) WO 97/25085
 - (9) US 5,210,083
 - (10) C. R. Pennington, A. D. Pithie, Journal of Parenteral and Enteral Nutrition, Vol. 11, No. 5, 1987, pages 507 to 508
 - (20) Excelsior Medical, Memo, filed by appellant 2 during the opposition proceedings, 2 pages
 - (20a) Study entitled "ASTM Partial Thromboplastin Time on 30% Ethanol in Water For Injection and 4% Citrate in Ethanol in Water For Injection", filed by appellant 2 during the opposition proceedings, pages 1 to 17
 - (21) In vitro Studies conducted at University of Southern California by M. Ryder, filed by appellant 2 during the opposition proceedings, 20 pages
- III. Notice of opposition had been filed by appellant 1 requesting revocation of the patent in suit in its entirety on the grounds of lack of novelty and inventive step, insufficiency of disclosure and added matter (Article 100(a), (b) and (c) EPC).

- IV. The decision under appeal was based on a main request (claims as granted) and auxiliary requests 1 and 2. The opposition division held that the subject-matter of claim 1 of the main request and claim 8 of auxiliary request 1 was anticipated by document (8). The division also considered that the subject-matter of claims 22 and 23 as granted, insofar as it covered the sequential use of the agents listed therein, had no basis in the application as originally filed. No objections under Articles 123(2) and (3), 84 and 83 EPC were raised against auxiliary request 2. Its subject-matter was considered to be novel and to involve an inventive step, starting either with document (5) or with document (10) as the closest prior art. In particular, the opposition division held that there was no motivation for the skilled person to mix the claimed alcohols with an anticoagulant. The division also admitted documents (20), (20a) and (21) into the proceedings.
- V. With the statement of grounds of appeal, appellant 1 maintained its objections of lack of novelty and inventive step, insufficiency of disclosure and added matter. In addition, it raised a new objection under Article 53(c) EPC.
- VI. With the statement of grounds of appeal, appellant 2 submitted a main request and a first auxiliary request. Auxiliary request 2, which the opposition division considered to comply with the requirements of the EPC, was maintained as second auxiliary request.
- VII. With letter of 30 May 2012, appellant 2 resubmitted the main request and filed new first and fourth auxiliary requests. The latter was subsequently replaced with an amended fourth auxiliary request (see point IX below). The previous first and second auxiliary requests (see

point VI above) were resubmitted as second and third auxiliary requests.

VIII. The main request consists of 23 claims with independent claims 1, 10, 22 and 23 reading as follows:

"1. An implantable catheter defining a lumen, the lumen containing a locking composition, wherein the locking composition comprises at least one lower alcohol selected from ethanol, propanol and butanol; and at least one other antimicrobial compound or at least one anticoagulant compound."

"10. A kit for locking an implantable catheter, said kit comprising a container holding a volume of a locking composition, wherein the locking composition comprises at least one lower alcohol selected from ethanol, propanol and butanol; and at least one other antimicrobial compound or at least one anticoagulant compound; and instructions for use setting forth a method comprising filling a lumen of the catheter with the composition."

"22. Use of a composition for locking an implantable catheter, the composition comprising at least one lower alcohol selected from ethanol, propanol and butanol; and at least one other antimicrobial compound or at least one anticoagulant compound."

"23. A locking composition for use in the prevention and/or treatment of infection and/or fouling of an implantable catheter, the locking composition comprising at least one lower alcohol selected from ethanol, propanol and butanol and at least one other antimicrobial compound; or at least one anticoagulant compound."

Independent claims 1 and 8 of the first auxiliary request differ from independent claims 1 and 10 of the main request in that the expression "implantable" has been substituted with the expression "implanted". Independent claim 22 of the main request has been maintained as independent claim 19 in a slightly amended form ("the composition comprising ..." has been replaced by "the locking composition comprising...") and independent claim 23 of the main request has been deleted.

Independent claims 1 and 8 of the second auxiliary request differ from claims 1 and 10 of the main request in that the locking composition comprises at least one lower alcohol selected from ethanol, propanol and butanol **and** at least one anticoagulant compound. The reference to the antimicrobial compound has been deleted. Independent claim 18 is identical to claim 19 of the first auxiliary request and independent claim 23 of the main request has been deleted.

The third auxiliary request differs from the second auxiliary request in that independent claim 18 and the dependent claims 19 to 26 have been deleted.

- IX. At the oral proceedings, in the course of discussion on novelty of claims 1 and 8 of the second auxiliary request, appellant 1 raised an objection of lack of novelty over document (9). Appellant 2 requested remittal of the case to the department of first instance, if this objection should be admitted. The request was discussed and subsequently refused by the board (see point 5 below).

In the course of discussion on the formal requirements under Rule 80, Article 123(2), (3) and 84 EPC, appellant 2 submitted an amended fourth auxiliary request in an attempt to address appellant 1's objection under Rule 80 EPC.

The amended fourth auxiliary request differs from the second auxiliary request in that the additional feature "whereby the concentration of the anticoagulant is about 4% by volume" has been introduced into independent claims 1, 8 and 18. Dependent claims 19 to 26, which had been objected to under Rule 80 EPC, have been deleted.

X. The arguments of appellant 1, as far as they concern the decisive issues, can be summarised as follows:

- Procedural matters

The main request and first to fourth auxiliary requests should not be admitted. They were filed late, raised new and complex issues, in particular with respect to Articles 123(2) and (3) EPC, 53c and 84 EPC. Appellant 1 could not reasonably be expected to deal with these issues at such a late stage. Furthermore, admission of the fourth auxiliary request might require remittal. Appellant 2's conduct was not in keeping with the purpose of the appeal proceedings, which was mainly to review the decision of the department of first instance, and was contrary to the need for procedural economy as laid down in Article 13(1) of the Rules of Procedure of the Boards of Appeal (RPBA). In addition, the sets of claim requests did not converge.

Documents (20), (20a) and (21) were filed by appellant 2 just two months before the oral proceedings before the opposition division. On such short notice, it was not

possible to verify the experimental results described therein or to provide counter experiments. The opposition division should not have admitted these documents or should have postponed the oral proceedings, if it considered them sufficiently relevant.

- Novelty

The subject-matter of claim 23 of the main request was anticipated by document (8), which disclosed the same compositions for the same purpose, namely to prevent infection and fouling of a catheter (see example on pages 30 and 31; page 4, line 13 ff, paragraph bridging pages 10 and 11). The statement of purpose in claim 23, which was directed to a product, did not limit the claim as far as non-medical uses were concerned. A medical treatment in the sense of treating an illness was also not supported, since the present invention was concerned with the treatment of infections of a catheter. Neither was the "locking composition" a limiting feature. It merely expressed the suitability of the composition for the purpose of filling the lumen of an implantable catheter. Document (8) also anticipated the claimed kit directed to a container comprising the claimed composition and instructions for use. Document (8) disclosed such compositions and inherently a container. The instructions for use were of a non-technical nature and had to be disregarded. Neither the package nor the leaflet, on which appellant 2 relied in its argumentation, were part of the claim.

Document (9) disclosed in example 18 a composition comprising ethanol and taurolidine. The latter was an anticoagulant as apparent from document (6). There was no reason to assume that ethanol in example 18 was incorrect or that the disclosed solution was not

suitable as a locking composition. Document (9) was therefore novelty destroying for the kit according to claim 8 of second and third auxiliary requests.

- Remittal

Novelty was a ground for opposition and within the proceedings. The objections in view of document (9) merely represented new arguments to an objection raised already in appellant 1's letter dated 17 May 2011.

- Amendments

The amendments in claims 1, 8 and 18 had no basis in the application as filed. The feature that the concentration of the anticoagulant was about 4% by volume was only disclosed in combination with specific anticoagulants (see claims 22 to 26 of the application as filed). The statement on page 8, line 20 was part of the content of a whole paragraph and could not be read in isolation. It referred to the preceding statements in this paragraph and linked the concentration with specific anticoagulants as did claims 22 to 26.

XI. The arguments of appellant 2, as far as they concern the decisive issues, can be summarised as follows:

- Procedural matters

All requests were filed with either the statement of grounds of appeal or the reply to the statement of grounds of appeal of appellant 1 and therefore within the time limits referred to in Articles 12 and 13 RPBA. In addition, the third auxiliary request was identical to auxiliary request 2 underlying the decision under appeal. The requests were essentially based on the

previously filed requests. Their subject-matter was not complex and their early submission gave appellant 1 sufficient opportunity to consider them and to provide further support for its argumentation, if this was necessary.

Documents (20), (20a) and (21) were filed within the time frame permitted under Rule 116(1) EPC and in direct response to a question raised in the opposition division's preliminary opinion. Their admission could therefore not be refused. Furthermore, they were considered to be relevant by the opposition division. Appellant 1 did not signal its intention to provide its own experimental data and did not request postponement of the oral proceedings in this respect.

- Novelty

Claim 23 of the main request was a second medical use claim and was drafted in the format permitted by decision G 2/08. It was directed to a locking composition which completely filled the lumen of an implantable catheter in order to prevent or treat infection/fouling of the catheter. Example 4.11 on pages 30/31 of document (8) did not disclose that the compositions completely filled the lumen of the catheter, remained there and thus acted as a locking composition. On the contrary, the aim of document (8) was to impregnate medical devices. It merely required contacting either the inner or the outer surface of the device with the compositions, but there was no requirement that the entire volume of the lumen be locked by the composition. Document (8) did also not anticipate the subject-matter of claim 8 of the first auxiliary request. This claim referred to an entity, such as a package, comprising a container and the

instructions for use in some sort of physical form, such as a leaflet. Not the content of the instruction, but their physical presence was decisive. Such an entity was not disclosed in document (8).

Example 18 of document (9) did not disclose a composition comprising the claimed components, since the disclosure in example 18 was apparently wrong. Moreover, this composition was not suitable as a locking composition due to the presence of all the additional components contained therein and the instability of the composition, which would clog the catheter.

- Remittal

The objection of lack of novelty over document (9) was filed late. It should not be admitted in view of the fact that the claims were identical with those considered by the opposition division to meet the requirement of the EPC (see point 3 on page 6 of the decision under appeal). If this objection was admitted, the case should be remitted to the department of first instance to provide appellant 2 with an opportunity to defend its position before two instances.

- Amendment

The amendment in the fourth auxiliary request was supported by the statement on page 8, line 20 of the application as originally filed, which referred to the concentration of the anticoagulant in general, and by claims 22 to 26 as originally filed.

XII. Appellant 1 requested that the appeal be set aside and that the patent be revoked. In addition appellant 1 requested that the Main Request and the 1st to 3rd

Auxiliary Requests submitted by appellant 2 under cover of a letter dated 30 May 2012, and documents D20, D20a and D21 not be admitted into the proceedings.

XIII. Appellant 2 requested that the decision under appeal be set aside and that the patent be maintained upon the basis of the Main Request, or alternatively upon the basis of any of the 1st to 3rd Auxiliary Requests, all claim requests being submitted under cover of a letter dated 30 May 2012, or alternatively upon the basis of the 4th Auxiliary Request, submitted at the oral proceedings before the board.

XIV. At the end of the oral proceedings the decision of the board was announced.

Reasons for the Decision

1. The appeal is admissible.

2. Procedural matters

2.1 Requests

2.1.1 Appellant 1 objected to the admission of all requests submitted with letter of 30 May 2012 (see point X above). In its reasoning, appellant 1 relied on principles laid down in Article 13 RPBA, which concerns amendments to a party's case after it has filed its grounds of appeal or reply. However, the main request and second and third auxiliary requests were submitted with the statement of grounds of appeal and the first auxiliary request was filed in reply to the statement of grounds of appeal of appellant 1 (see point VII above). Thus, Article 12 RPBA, which stipulates the basis of the

appeal proceedings, rather than Article 13 RPBA applies in the present case.

2.1.2 Article 12(4) RPBA requires the board to take into account everything presented by the parties under Article 12(1) RPBA if and to the extent that it relates to the case under appeal and meets the requirements in Article 12(2) RPBA. However, according to Article 12(4) RPBA, the board has the discretionary power to hold inadmissible facts, evidence or requests which could have been presented or were not admitted in the first-instance proceedings. When exercising its discretion the board has to consider the specific circumstances of the case bearing in mind that the purpose of an appeal is to offer the losing party the possibility to challenge the decision of the opposition division on its merits, and not to conduct the case anew. While this does not preclude new submissions, their admission is restricted. Submissions which can be considered as a normal reaction of a losing party given the circumstance are usually allowed into the appeal proceedings by the boards.

2.1.3 Appellant 2's main request basically corresponds to the main request (claims as granted) underlying the decision under appeal, which had been refused by the opposition division, except for the reformulation of independent claims 22 and 23 as granted. According to appellant 2, these amendments took into consideration the opposition division's objection concerning these claims (see point 1.1, last paragraph of the Reasons of the contested decision). Furthermore, claim 23 was redrafted in view of decision G 2/08. The board understands that appellant 1 had additional objections against the reformulated claims. However, in the board's opinion, the reformulation does not raise complex issues or creates a "fresh case", thereby rendering the decision under

appeal obsolete and requiring the board to conduct the case completely anew. The same applies to the second auxiliary request, which is largely based on the auxiliary request 2 of the decision under appeal and, in addition, contains the reformulated claim 22 of the main request.

The first auxiliary request was filed in response to the statement of grounds of appeal by appellant 1. In particular, auxiliary request 1 was filed in reply to an objection, which had been raised for the first time in the appeal proceedings by appellant 1.

The third auxiliary request has been introduced into the proceedings before the first instance and has been decided on by the opposition division. In its statement of grounds of appeal, appellant 2 maintained this request as its second auxiliary request, which subsequently became the third auxiliary request (see points V and VI above). Accordingly, Article 12(4) RPBA does not apply and this request forms part of the appeal proceedings pursuant to Article 12(1) and (2) RPBA. Appellant 1 did not argue that the division had not correctly exercised its discretion in admitting this request.

2.1.4 Hence, given the circumstances, the submission of appellant 2's requests, which, in addition, have been filed without delay at the earliest possible stage in the appeal proceedings are considered to be a normal and legitimate reaction of appellant 2 to defend the maintenance of the patent in suit. Moreover, in view of the early filing (i.e. about three years before oral proceedings before the board), appellant 1 had ample time and opportunity to prepare its defence and to provide additional evidence, if so required. Hence, the

board is convinced that appellant 1's right to be heard has been fully respected.

- 2.1.5 Concerning appellant 1's objection of diverging requests, the board notes that divergence is one of several criteria, on which the admissibility of amended requests may depend. It belongs to the discretion of the boards of appeal to decide which criteria are to have precedence according to the circumstances of the case (see R 16/09, point 2.2.11 of the Reasons). In the present case, the board notes that the various sets of claims only slightly diverge without completely changing the direction of the claimed subject-matter. The focus has been and still is essentially on the locking composition. Moreover, all requests were filed at an early stage in the proceedings. In these circumstances, irrespective of their slight divergence, the board sees no reason not to admit appellant 2's requests.
- 2.1.6 In the written proceedings, appellant 1 also argued that appellant 2's requests did not comply with Rule 137(4) EPC and should therefore not be admitted.
- 2.1.7 The board notes that Rule 137 EPC concerns amendments of the European patent application during the examination proceedings. It is therefore questionable whether this rule is applicable in opposition appeal proceedings. However, this question can be left undecided, since even if it is applicable, it has been complied with. Appellant 2 has identified the amendments made in its requests and indicated the basis for these amendments in the application as filed (see point 2 of statement of grounds of appeal and point 4 of the reply to the statement of grounds of appeal of appellant 1).

2.1.8 For the aforementioned reasons, the board decided to admit appellant 2's main and first to third auxiliary requests into the proceedings.

2.1.9 The fourth auxiliary request was filed at the oral proceedings (see point IX above). Its claims are identical to claims 1 to 18 of the fourth request filed in reply to the statement of grounds of appeal of appellant 1 dated 30 May 2012. The deletion of former claims 19 to 24 in an attempt to overcome an objection under Rule 80 EPC had not been objected to by appellant 1. As a consequence, the reasoning set out in points 2.1.1 to 2.1.7 above also applies to the fourth auxiliary request. It is additionally noted that the subject-matter of the fourth auxiliary reflects more closely appellant 2's experimental data in support of inventive step filed in the opposition proceedings. It does not deviate to such an extent from the line of defence followed during the opposition proceedings that the decision under appeal is rendered pointless or that the board is faced with an entirely new case. Accordingly, it was admitted into the proceedings.

2.2 Documents (20), (20a) and (21)

2.2.1 In exercising its discretion under Article 114(2) EPC, the opposition division decided to admit these documents into the proceedings.

This decision was challenged by appellant 1, who argued that the opposition division did not exercise its discretion correctly (see point X above).

2.2.2 If a discretionary decision of the opposition division is challenged, it is not the task of the board to review all facts and circumstances as if it were in the place

of the first instance, and to decide whether or not it would have exercised such discretion in the same way. The board should only overrule the way in which the opposition division has exercised its discretion if it comes to the conclusion that it has done so without taking into account the right principles, or that it had exercised its discretion in an unreasonable way and has thus exceeded the proper limit of its discretion (see G 7/93, OJ EPO 1994, 775, point 2.6 of the Reasons).

- 2.2.3 The admission of the documents was discussed with the parties in the oral proceedings before the opposition division. This was not contested. In the decision under appeal, the opposition division explained that documents (20), (20a) and (21) were submitted in response to the division's communication attached to the summons to oral proceedings. They were filed within the time limit set by the division in accordance with Rule 116(1) EPC and were considered to be relevant for the assessment of inventive step as an attempt to address the division's concerns with respect to existence of convincing support for the alleged effects mentioned in column 3, lines 39 to 45 of the patent in suit (see decision under appeal, point 3.2 of the Reasons and summons, point 5 on page 11). Since the opposition division considered the relevance of these documents and came to a positive result, the board sees no reason to doubt that the opposition division has exercised its discretion correctly and in a reasonable way, taken into account that relevance is an important criterion in deciding whether or not to admit new documents, facts of evidence. Whether or not the opposition division erred in its assessment as to the relevance of documents (20), (20a) and (21), as argued by appellant 1, is not relevant in this context, but rather needs to be considered in the assessment of inventive step.

The board also notes that appellant 1 in its reply to the submission of documents (20) (20a) or (21) did not indicate its intention to submit own experimental data in order to refute appellant 2's results and that more time was needed for that purpose. Nor did appellant 1 request postponement of the oral proceedings. Instead it chose to limit itself to argue on the admissibility of documents (20), (20a) and (21). However, in the board's opinion, it could not have relied on the fact that the opposition division would exercise its discretion in appellant 1's favour and not admit these documents. Nor was the opposition division, in these circumstances, obliged to postpone the oral proceedings.

- 2.2.4 For the aforementioned reasons, the board sees no reasons to overrule the opposition division's decision to admit documents (20), (20a) and (21). Nor does the board agree with appellant 1's allegation that its right to be heard is violated if these documents are considered in the appeal proceedings. Since they have been filed more than four years ago, appellant 1 had sufficient time to consider these documents and to produce, if necessary, its own experimental data.

Main request

3. Novelty

- 3.1 Independent claim 23 is drafted in the form of a purpose-related product claim pursuant to Article 54(5) EPC. This article acknowledges the novelty of substances or compositions, even if they form part of the prior art, provided they are claimed for a new use in a method, which is excluded pursuant to Article 53(c) EPC, such as a method for treatment of the human/animal

body by therapy. However, if this is not the case, a statement of purpose of a claimed product is, according to established jurisprudence of the boards of appeal, to be interpreted as meaning that the product is suitable for the stated purpose.

3.2 In the present case, claim 23 refers to a locking composition for use in the prevention and or treatment of infection or fouling of an implantable catheter, the locking composition comprising at least one alcohol selected of ethanol, propanol or butanol and at least one antimicrobial or anticoagulant compound. In spite of its format, this claim does not reflect a therapeutic method, since it does not involve the treatment or alleviation of an illness or pathological condition, which, in the board's judgement requires that the active agent is administered to the human or animal body, where it can exert its therapeutic function (see T 611/09, point 4.1.1 of the Reasons). On the contrary, claim 23 is directed to a method of disinfecting a catheter, including impregnation with a disinfectant/ anticoagulant, before the catheter even comes in contact with the human body. In this context, the board notes that the term "locking composition" has no specific or in anyway limiting meaning, except that it is suitable to fill (lock) the lumen of the catheter (i.e. suitable to act as a locking composition).

3.3 It follows from points 3.1 and 3.2 above that claim 23 is directed to a composition which is suitable for filling the lumen of an implantable catheter and suitable for preventing and/or treating infections/ fouling of such a catheter, the composition comprising the claimed alcohol and antimicrobial or anticoagulant compound.

3.4 Document (8) discloses solutions comprising ethanol and the anti-infective agents chlorohexidine and triclosan (see page 30, line 20 to page 32, line 10, page 2, lines 8 to 10, page 16, line 24 to page 17, line 34). These solutions are undoubtedly suitable to fill the lumen of an implantable catheter (see also page 11, lines 4 to 6 of document (8)) and to prevent or treat infections therein.

3.5 Hence, the board concludes that the subject-matter of claim 23 of the main request is not novel over document (8) (Article 54 EPC), with the consequence that the main request must be refused.

First auxiliary request

4. Novelty

4.1 Claim 8 of the first auxiliary request is directed to a kit for locking an implanted catheter. The kit comprises a container holding a volume of a locking composition, which comprises at least one alcohol selected from ethanol, propanol and butanol and at least one other antimicrobial compound or anticoagulant compound and instructions for use.

4.2 The board agrees with the opposition division's findings that the instructions for use are non-technical in nature. They contain information on how to use the claimed product without having a technical effect on the product itself or affecting its properties as antimicrobial/anticoagulating locking composition. These properties are solely the consequence of the chemical nature of the components and are independent of any instructions. In other words there exists no functional relationship between the composition and the

instructions, which can be seen as a contribution to the technical character of the claimed subject-matter.

According to established jurisprudence of the boards of appeal, non-technical features, which do not provide a technical contribution, do not limit the scope of a claim and cannot be considered in the evaluation of novelty or inventive step (see T 553/02, points 1.3 in combination with point 1.2.2 of the Reasons; T 784/06, point 4 of the Reasons). The board therefore concurs with the opposition division that the instructions for use are to be disregarded in the examination of novelty.

- 4.3 The board also concurs with the opposition division's understanding of claim 8 as being directed to a container holding a volume of a composition suitable for locking the lumen of a catheter, whereby the composition comprises at least one of the claimed alcohols and at least one antimicrobial or anticoagulant compound. This understanding is not changed by the fact that claim 8 of the present request refers to a locking composition for an implanted catheter instead of an implantable catheter as in the request underlying the contested decision.
- 4.4 According to established jurisprudence of the boards of appeal a prior art document anticipates the novelty of the claimed subject-matter, if the latter is directly and unambiguously derivable from that document, including any feature implicit to a person skilled in the art. In this context implicit disclosure means no more than the clear and unambiguous consequence of what is explicitly disclosed (see T 1537/07, 2.4 of the Reasons).
- 4.5 As explained in point 3.4 above, compositions comprising the claimed components are known from document (8). They

are suitable for locking the lumen of the catheter, irrespective of whether the catheter is implanted or not. This was not contested by appellant 2. In view of the fact that the compositions on pages 30/31 of document (8) are liquid in nature, the presence of a container holding such a composition is also necessary implied and can be directly and unambiguously inferred from the disclosure of that document.

4.6 According to appellant 2, claim 8 was novel because it was directed to a physical entity, such as a package for holding the container and the instructions in the form of a leaflet. In this context, appellant 2 referred to the description of the patent in suit. Such an entity was not disclosed in document (8). However, neither "a package" nor the means of providing the instructions are part of the claim. Appellant 2's argument cannot therefore succeed.

4.7 Hence, the board concludes that the subject-matter of claim 8 of the first auxiliary request is not novel within the meaning of Article 54 EPC and the request must be refused.

Second and third auxiliary requests

5. Request for remittal

5.1 At the oral proceedings before the board, appellant 1 raised an objection of lack of novelty against claims 1 and 8 of the second auxiliary request in view of document (9). Appellant 2 requested remittal of the case to the opposition division, if this objection should be considered by the board (see point XI above).

- 5.2 It is established jurisprudence of the boards of appeal that there is no absolute right to have an issue decided upon by two instances. Article 111(1) EPC leaves it to the discretion of the board to exercise any power within the competence of the department of first instance or to remit the case to that department taking due account of the circumstances of the case.
- 5.3 The board notes that in the present case, lack of novelty does not constitute a fresh ground for opposition and its consideration by the board is not prohibited. It was raised as a ground for opposition in the notice of opposition. It was substantiated therein and considered by the opposition division in the decision under appeal. This is not changed by the fact that appellant 1 did not object to the novelty of the claims of auxiliary request 2 underlying the decision under appeal. In this context, the board concurs with the position of the board in the decision T 764/06 where it is stated that "a ground of opposition, once it has been validly raised, continues to belong to the legal and factual framework of the opposition according to Rule 76(c) EPC" (see T 764/06, point 3.5 of the Reasons).
- 5.4 The board also notes that, in its statement of grounds of appeal, appellant 1 had cited document (9) as novelty destroying for the subject-matter of the patent in suit. The respective passages in document (9) supporting appellant 1's view were also clearly indicated (see page 30 of the statement of grounds of appeal). In addition, the board notes that document (9) was not a new document filed for the first time in the appeal proceedings, but had already been filed with the notice of opposition. In this respect, the present case differs from those cases where the boards have ordered remittal to the department

of first instance, because a new document which was found relevant enough to be taken into consideration had been filed for the first time in appeal proceedings. Furthermore, in the board's judgment, appellant 1's submission with respect to lack of novelty is not based on new facts and evidence, but rather on additional arguments concerning the known properties of the components of the composition disclosed in document (9), in particular the known antimicrobial and anticoagulating activity of taurolidine.

- 5.5 For the aforementioned reasons and taking into consideration that remittal would unnecessarily delay the proceedings, the board considered it not appropriate to remit the case to the department of first instance.

6. Novelty

6.1 Claim 8 of the second auxiliary request is identical to claim 8 of the first auxiliary request, with the exception that the catheter is implantable and the locking composition comprises one of the specifically claimed alcohols **and** an anticoagulant compound. Hence, with respect to the feature "instructions for use" and the understanding of the claim, the same considerations as in points 4.2. and 4.3 apply.

6.2 Document (9) discloses in example 18 a solution, which comprises, amongst other ingredients, ethanol and taurolidine. The latter is an antimicrobial as well as an anticoagulant compound, which is confirmed by document (6) (see column 1, lines 20 to 21 and 40 to 42). Additional ingredients such as those disclosed in example 18 are encompassed in claim 8 of the second auxiliary request due to the open formulation of the locking compositions (i.e. "wherein the locking composition **comprises**"). The solution in example 18 is suitable to fill the lumen of an implantable catheter. Moreover, the solution, being a liquid formulation for parenteral infusion or injection, requires necessarily a container. Thus, for the same reasons as set out in points 4.4 and 4.5 above, the subject-matter of claim 8 of the second auxiliary request, is not novel over document (9).

6.3 According to appellant 2, example 18 could not anticipate the claimed subject-matter, because this example would have been disregarded by the person skilled in the art as incorrect or at least ambiguous. In the list of ingredients "ethanol" was mentioned as a component under the heading "Polyols". However, ethanol was clearly not a polyol. Moreover, the solution

disclosed in example 18 was not suitable as a locking composition. Rather it represented a culture medium for bacteria, taking into account all the additional ingredients being present therein. Appellant 2 also argued that the solution was not stable and would therefore lead to the clogging of the catheter.

- 6.4 The board sees no reason for the assumption that the person skilled in the art would ignore an explicitly mentioned ingredient for the sole reason that it was not properly classified. On the contrary, in the board's opinion the skilled person would take the list of ingredients as disclosed unless this would be technically unreasonable. For example, the presence of such an ingredient would render the solution unsuitable for the intended purpose. No such technical reasons are apparent to the board and none have been provided by appellant 2. Concerning the alleged unsuitability as locking composition, the board notes that taurolidine is an effective antimicrobial and is administered in document (9) to treat infections. It is therefore not credible that its incorporation into the solution disclosed in example 18 leads to a culture medium for bacteria, irrespective of the presence of other ingredients, which may favour bacterial growth. With respect to the alleged instability, the board notes that document (9) indeed mentions that there is some evidence that reactions can occur at elevated temperature (see column 3, line 59 to column 4, line 17). However, the document also mentions that no difficulties exist, if certain precautions, which are explicitly described, are taken (see column 4, lines 17 to 22).

- 6.5 Hence the board concludes that the subject-matter of claim 8 of the second auxiliary request and, due to the identical wording, the subject-matter of claim 8 of the

third auxiliary request is not novel within the meaning of Article 54 EPC, with the consequence that both requests must be refused.

Fourth auxiliary request

7. Amendments

7.1 Independent claims 1 and 8 of the fourth auxiliary request differ from the corresponding claims 1 and 10 as granted in that the locking composition has been limited to a composition comprising at least one of the specifically claimed alcohols **and** at least one anticoagulant. In addition, the concentration of the anticoagulant (i.e. about 4% by volume) has been introduced. The same limitations have also been introduced into the reformulated claim 18 (claim 22 as granted).

7.2 According to appellant 2 these amendments find support on page 8, line 20 of the application as originally filed and claims 22 to 26 as originally filed.

7.2.1 Dependent claims 22 to 26 as originally filed are directed to specific embodiments of the implantable catheter according to claims 11-13, wherein the locking composition for the catheter comprises **specific** anticoagulants (i.e. riboflavin, sodium citrate, ethylene diamine tetraacetic acid and citric acid) in combination with a **specific** amount (i.e. about 4% volume).

7.2.2 On page 8, line 20 it is stated that "A preferred concentration of the anti-coagulant is about 4% by volume". However, the board notes that appellant 2 has isolated this statement from the content of a whole

paragraph. In order to establish what is clearly and unambiguously disclosed due account has to be taken of the proper context in which the statement is set.

The paragraph on page 8, lines 10 to 23 of the application as filed discloses preferred locking compositions for implantable catheters, which include a lower alcohol in the range of 1 to 99% and specific antimicrobials (taurolidine, triclosan) or specific anticoagulants (riboflavin, sodium citrate, ethylene diamine and citric acid) in the range of 1 to 99%. This disclosure is followed by the aforementioned statement that a preferred concentration of the anticoagulant is about 4% by volume, and subsequently the most preferred locking composition is defined wherein the concentration of isopropanol is about 17.5% by volume and sodium citrate is about 4% by volume. Read in its proper context, the statement relied on by appellant 2, discloses a further limitation in the concentration of the **specific** anticoagulants immediately preceding this statement and not, as argued by appellant 2, a preferred concentration of the anticoagulant compound in general.

- 7.3 It follows that none of the passages relied on by appellant 2 provides a clear and unambiguous basis for the claimed concentration of the anticoagulant in general. Rather, the introduction of this feature into independent claims 1, 8 and 18 amounts to an intermediate generalisation, which according to established jurisprudence of the boards of appeal is justified only if the skilled person could recognise without any doubts from the application as filed that the isolated feature was not closely associated with the others feature or features and applied directly and unambiguously to the more general context (see for example T 1067/97, point 2.1.3 of the Reasons). In the

present case, the claimed concentration may have been adapted to the specifically mentioned compounds in order to achieve the desired activity. In the absence of any indication to the contrary, it is therefore not clearly and unambiguously recognisable for the person skilled in the art that the concentration and the respectively disclosed anticoagulants were not closely associated.

- 7.4 Hence, the board concludes that the fourth auxiliary request does not comply with the requirements of Article 123(2) EPC, with the consequence that this request must also be refused.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The patent is revoked.

The Registrar:

The Chairman:



M. Schalow

A. Lindner

Decision electronically authenticated